

US3952033 (Prod: Synexus - Optimal Research - Rockville)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:33:44

All time stamps listed in this document are displayed in GMT

US3952033

Form: Participant Creation

Data signed: (b) (4) 07 Apr 2021 21:10:05

Generated On: 10 Jun 2021 10:33:44

[Participant ID](#)

US3952033

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

US3952033

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3952033

Folder: Screening

Form: Demographics

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	52
Age Units	YEARS
Age (Derived)	52
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

US3952033

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Date of Informed Consent (dd MMM yyyy)	02 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3952033

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3952033

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Were any significant conditions reported?

Yes ☒

No ☐

US3952033

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	CHRONIC SINUSITIS
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952033

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	ANTIPHOSPHOLIPID SYNDROME
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

US3952033

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	RHEUMATOID ARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952033

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3952033

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	CHRONIC PAIN SYNDROME
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952033

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3952033

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952033

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	RHUEMATOID ARTHRITIS FLARE
Start date (dd MMM yyyy)	UN MAR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN APR 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	APR 2020
Stop Year (derived)	2020

US3952033

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

US3952033

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	RIGHT TOTAL KNEE ARTHROPLASTY
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

US3952033

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	LEFT TOTAL KNEE ARTHROPLASTY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3952033

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	LEFT ANKLE RECONSTRUCTION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

US3952033

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	SEVERE OBESITY
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	_____

US3952033

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	HERPES SIMPLEX I
Start date (dd MMM yyyy)	UN UNK 1976
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1976
Start Year (derived)	1976
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952033

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

US3952033

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	02 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:52 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 13:52
Height (<i>xxx.x</i>)	65.0 in
Weight (<i>xxx.x</i>)	293.0 lb
BMI (<i>xxx.x</i>)	48.85970 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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)	

US3952033

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3952033

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Date of assessment (dd MMM yyyy) 02 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2009

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

US3952033

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

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

US3952033

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

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)	True
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)	False
Other	True
Specify	LIVES WITH TWO ESSENTIAL WORKERS, NO LIFESTYLE CHANGE I.E. NOT SHELTERING IN PLACE.

US3952033

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3952033

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 145311

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Height	ND - Not Done
Weight	ND - Not Done

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	02 SEP 2020
Time of assessment (00:00-23:59)	13:52 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 13:52
Temperature (xxx.x)	37.3 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	103 mmHg
Diastolic Blood Pressure units	MMHG

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	02 SEP 2020
Time of assessment (00:00-23:59)	16:57 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 16:57
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3952033

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

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.

US3952033

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

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) 02 SEP 2020

What was the treatment time? (00:00-23:59) 16:09 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 16:09

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

US3952033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 SEP 2020

Collection time (00:00-23:59)

14:50 (24 HR)

Collection date and time (derived)

02 SEP 2020 14:50

US3952033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:36	02 SEP 2020 14:36
Nasopharyngeal Swab 2	No		

US3952033

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

02 SEP 2020 17:09

PC Open Date & Time

02 SEP 2020 16:29

PC Close Date & Time

02 SEP 2020 18:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °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):

To **TREAT** pain or fever that has already occurred True

To **PREVENT** pain or fever from occurring False

PC Time Stamp 02 SEP 2020 20:04

PC Open Date & Time 02 SEP 2020 19:54

PC Close Date & Time 03 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.8 °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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	03 SEP 2020 17:44
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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):

To **TREAT** pain or fever that has already occurred False

To **PREVENT** pain or fever from occurring True

PC Time Stamp 04 SEP 2020 21:27

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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):

To **TREAT** pain or fever that has already occurred

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

05 SEP 2020 21:44

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	06 SEP 2020 20:09
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:33:44

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	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	07 SEP 2020 19:21
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	08 SEP 2020 20:37
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 8

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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	09 SEP 2020 19:59
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☒

No ☐

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

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

10 SEP 2020 22:25

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 10

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.6 °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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	12 SEP 2020 08:37
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 11

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

To **TREAT** pain or fever that has already occurred True

To **PREVENT** pain or fever from occurring True

PC Time Stamp 12 SEP 2020 22:09

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 12

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True

To PREVENT pain or fever from occurring	True

PC Time Stamp	14 SEP 2020 01:24

PC Open Date & Time	13 SEP 2020 12:00

PC Close Date & Time	14 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 13

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.5 °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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	14 SEP 2020 23:29
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 14

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	15 SEP 2020 20:57
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 15

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 23:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

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

02 SEP 2020 17:09

PC Open Date & Time

02 SEP 2020 16:29

PC Close Date & Time

02 SEP 2020 18:59

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

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 ☐

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

4

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☒

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

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

02 SEP 2020 20:17

PC Open Date & Time

02 SEP 2020 19:54

PC Close Date & Time

03 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:33:44

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 ☐

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

4

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☒

No ☐

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

50

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 17:42

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:33:44

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

04 SEP 2020 21:28

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:33:44

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

05 SEP 2020 21:44

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:33:44

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

06 SEP 2020 20:06

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:33:44

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

07 SEP 2020 19:21

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:33:44

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

08 SEP 2020 20:38

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

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 ☐

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 17:10
PC Open Date & Time	02 SEP 2020 16:29
PC Close Date & Time	02 SEP 2020 18:59

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

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 ☐

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 20:18
PC Open Date & Time	02 SEP 2020 19:54
PC Close Date & Time	03 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

65 of 4253

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

Yes ☐	
PC Time stamp	03 SEP 2020 17:43
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

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)

67 of 4253

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

Yes ☐	
PC Time stamp	04 SEP 2020 21:30
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

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

69 of 4253

EAB) (1725)

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

Yes ☐	
PC Time stamp	05 SEP 2020 21:45
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

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

71 of 4253

EAB) (1725)

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

Yes ☐	
PC Time stamp	06 SEP 2020 20:03
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

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)

73 of 4253

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

Yes ☐	
PC Time stamp	07 SEP 2020 19:22
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

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)

75 of 4253

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

	Yes ☐
PC Time stamp	08 SEP 2020 20:39
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 SEP 2020 19:59

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 10 SEP 2020 22:26

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

12 SEP 2020 08:37

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

12 SEP 2020 22:09

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

14 SEP 2020 01:24

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

14 SEP 2020 23:29

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

15 SEP 2020 20:57

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

16 SEP 2020 23:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

17 SEP 2020 22:21

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 09 SEP 2020 20:00

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 10 SEP 2020 22:26

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

12 SEP 2020 08:37

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time stamp

12 SEP 2020 22:09

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

14 SEP 2020 01:24

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

14 SEP 2020 23:29

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 15 SEP 2020 20:57

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

16 SEP 2020 23:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

17 SEP 2020 22:21

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 09 SEP 2020 20:00

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 10 SEP 2020 22:26

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 12 SEP 2020 08:37

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time stamp

12 SEP 2020 22:09

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

14 SEP 2020 01:24

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 14 SEP 2020 23:29

PC Open Date & Time 14 SEP 2020 12:00

PC Close Date & Time 15 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 15 SEP 2020 20:57

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 16 SEP 2020 23:01

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 SEP 2020 22:21

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	09 SEP 2020 20:00
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	10 SEP 2020 22:26
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	12 SEP 2020 08:38
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	12 SEP 2020 22:09
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	14 SEP 2020 01:24
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	14 SEP 2020 23:29
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	15 SEP 2020 20:57
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	16 SEP 2020 23:01
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	17 SEP 2020 22:22
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 8

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 09 SEP 2020 20:01

PC Open Date and Time 09 SEP 2020 12:00

PC Close Date and Time 10 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 9

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 10 SEP 2020 22:27

PC Open Date and Time 10 SEP 2020 12:00

PC Close Date and Time 11 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 10

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 08:38

PC Open Date and Time

11 SEP 2020 12:00

PC Close Date and Time

12 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 11

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 12 SEP 2020 22:10

PC Open Date and Time 12 SEP 2020 12:00

PC Close Date and Time 13 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 12

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 01:24

PC Open Date and Time

13 SEP 2020 12:00

PC Close Date and Time

14 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 13

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 23:29

PC Open Date and Time

14 SEP 2020 12:00

PC Close Date and Time

15 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 14

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 20:58

PC Open Date and Time

15 SEP 2020 12:00

PC Close Date and Time

16 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(15)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 15

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 16 SEP 2020 23:01

PC Open Date and Time 16 SEP 2020 12:00

PC Close Date and Time 17 SEP 2020 11:59

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(16)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

DAY 16

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 22:22

PC Open Date and Time

17 SEP 2020 12:00

PC Close Date and Time

18 SEP 2020 11:59

US3952033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952033

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952033

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952033

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

Timepoint	Pre-Dose ☒
	Post-Dose ☐
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	

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

Timepoint	Pre-Dose ☐
	Post-Dose ☒
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	

US3952033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

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.

US3952033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☒
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3952033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3952033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

Collection date (dd MMM yyyy)

Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3952033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

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

US3952033

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

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

US3952033

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

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

US3952033

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

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) _____

US3952033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

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.

US3952033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 NOV 2020

Collection time (00:00-23:59)

16:19 (24 HR)

Collection date and time (derived)

11 NOV 2020 16:19

US3952033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:11:11

Generated On: 10 Jun 2021 10:33:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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	18 DEC 2020 14:42:31
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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 DEC 2020 08:33:27

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

01 JAN 2021 00:02:00

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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	08 JAN 2021 10:22:28
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

17 JAN 2021 13:38:11

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3952033

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:33:44

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

US3952033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

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

US3952033

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952033

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 07 Apr 2021 21:10:06

Generated On: 10 Jun 2021 10:33:44

Date of Contact	07 OCT 2020
Time of Contact	17:40
Date and Time of Contact (derived)	07 OCT 2020 17:40
Type of Contact	Clinic Visit - Scheduled☐ Clinical Visit - Unscheduled☐ Safety Call☐ Convalescent Tele-visit☒
Has the subject reported symptoms of SARS-COV-2?	Yes☒ No☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	101.3 F	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		173 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

	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	☒

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	04 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		177 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

	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	☒

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		181 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

	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	☒

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	06 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		185 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

	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	☒

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	101.9 F	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		189 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

	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	☒

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	102.2 F	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		193 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 OCT 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	103.1 F	
Chills	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		197 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	10 OCT 2020

Assessment Not Done	False

O2 Saturation	93 %

O2 Saturation Units	%

Temperature	103.7 F

Chills	None ☐
	Mild ☒
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☐
	Mild ☒
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☐
	Mild ☐
	Moderate ☒
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Fatigue	None ☐

PRODUCTION RELEASE (v12.003 EAB) (1725)	201 of 4253

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 OCT 2020	
Assessment Not Done	False	
O2 Saturation	89 %	
O2 Saturation Units	%	
Temperature	101.9 F	
Chills	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		205 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	102.7 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		209 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 OCT 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	102.1 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		213 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	14 OCT 2020

Assessment Not Done	False

O2 Saturation	95 %

O2 Saturation Units	%

Temperature	98.4 F

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☐
	Mild ☒
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☐
	Mild ☒
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Fatigue	None ☐

PRODUCTION RELEASE (v12.003 EAB) (1725)	217 of 4253

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☒
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.6 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		221 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☒
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		225 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☒
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		229 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☒
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	18 OCT 2020

Assessment Not Done	False

O2 Saturation	99 %

O2 Saturation Units	%

Temperature	98.2 F

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☐
	Mild ☒
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Fatigue	None ☐

PRODUCTION RELEASE (v12.003 EAB) (1725)	233 of 4253

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☒
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	19 OCT 2020

Assessment Not Done	False

O2 Saturation	99 %

O2 Saturation Units	%

Temperature	98.2 F

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☐
	Mild ☒
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Fatigue	None ☐

PRODUCTION RELEASE (v12.003 EAB) (1725)	237 of 4253

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☒
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

241 of 4253

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☒
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
PRODUCTION RELEASE (v12.003		245 of 4253
EAB) (1725)		

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☒
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	22 OCT 2020

Assessment Not Done	False

O2 Saturation	99 %

O2 Saturation Units	%

Temperature	98.5 F

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Fatigue	None ☐

PRODUCTION RELEASE (v12.003 EAB) (1725)	249 of 4253

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☒
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	23 OCT 2020

Assessment Not Done	False

O2 Saturation	99 %

O2 Saturation Units	%

Temperature	97.8 F

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Fatigue	None ☐

PRODUCTION RELEASE (v12.003 EAB) (1725)	253 of 4253

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☒
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	24 OCT 2020

Assessment Not Done	False

O2 Saturation	99 %

O2 Saturation Units	%

Temperature	97.9 F

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Fatigue	None ☐

PRODUCTION RELEASE (v12.003 EAB) (1725)	257 of 4253

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☒
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	25 OCT 2020

Assessment Not Done	False

O2 Saturation	99 %

O2 Saturation Units	%

Temperature	97.9 F

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Fatigue	None ☒

PRODUCTION RELEASE (v12.003 EAB) (1725)	261 of 4253

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

	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	☐

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 07 Apr 2021 21:10:05

Generated On: 10 Jun 2021 10:33:44

Date of Visit 08 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 08 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 09 Apr 2021 20:15:21

Generated On: 10 Jun 2021 10:33:44

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 09 OCT 2020
End Date 11 OCT 2020
Oxygen Saturation 89 %

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

If Yes, provide:

Start Date _____
End Date _____
PaO₂ ND - Not Done

Did the subject have Respiratory failure? Yes ☐
No ☒

Start Date _____

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

Start Date _____

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 09 Apr 2021 20:15:21

Generated On: 10 Jun 2021 10:33:44

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

266 of 4253

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 09 Apr 2021 20:15:21

Generated On: 10 Jun 2021 10:33:44

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

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 07 Apr 2021 21:10:06

Generated On: 10 Jun 2021 10:33:44

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	10 OCT 2020
Day 5	Yes	12 OCT 2020
Day 7	Yes	14 OCT 2020
Day 9	Yes	16 OCT 2020
Day 14	Yes	21 OCT 2020
Day 21	Yes	28 OCT 2020
Day 28	Yes	04 NOV 2020

US3952033

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☒
	Clinic ☐
Folder OID	SICKD1

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 OCT 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 10:10
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	37.5 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952033

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

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.

US3952033

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

08 OCT 2020

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:10:05

Generated On: 10 Jun 2021 10:33:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:10:05

Generated On: 10 Jun 2021 10:33:44

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	04 NOV 2020
Time of assessment (00:00-23:59)	13:34 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 13:34
Height (xxx.x)	65.0 in
Weight (xxx.x)	282.5 lb
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:10:05

Generated On: 10 Jun 2021 10:33:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 NOV 2020

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

US3952033

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 07 Apr 2021 21:10:05

Generated On: 10 Jun 2021 10:33:44

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

04 NOV 2020

US3952033

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

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	UNBLND_DECIDE

US3952033

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

Form: Unblinding

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ☒
Actual Dose 1	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☐ Not Administered ☒
Will participant receive mRNA-1273?	Yes ☐ No ☒
Placebo Only Flag	1
Continuing with mRNA-1273	

US3952033

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	14 JAN 2021

Collection time (00:00-23:59)	17:07 (24 HR)

Collection date and time (derived)	14 JAN 2021 17:07

US3952033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	17:08
Collection Date and Time (derived)	14 JAN 2021 17:08

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Visit Date

Please check all assessments that apply for this visit

Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:11:10

Generated On: 10 Jun 2021 10:33:44

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	02 SEP 2020
Time of assessment (00:00-23:59)	14:01 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 14:01
Temperature (xxx.x)	37.3 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952033

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 04 Nov 2020 22:15:32

Generated On: 10 Jun 2021 10:33:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

AEID

Adverse event

HERPES SIMPLEX I
EXACERBATION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

285 of 4253

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

AEID	USA-US215-2020-MRNA-1273-P30 1000001
Adverse event	GASTRITIS W/ INTRACTABLE VOMITING
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	23 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	30 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
PRODUCTION RELEASE (v12.003 EAB) (1725)	287 of 4253

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

SUBJECT REPORTS ADMISSION
IN HOSPITAL ON 23 SEP 2020
FOR FOOD POISONING, PER
PATIENT REPORT. STILL IN
HOSPITAL. WILL FOLLOW
APPROPRIATELY AND OBTAIN
MEDICAL RECORDS UPON
DISCHARGE.

SAE UPDATE PER MEDICAL
RECORDS
CLARIFY ADMIT DATE
26SEP2020
DISCHARGE DATE 30SEP2020

PT PRESENTED WITH
INTRACTABLE NAUSEA AND
VOMITING. WAS GIVEN
COMPAZINE ALONG WITH A
CLEAR LIQUID DIET. EGD
REVEALED MILD
INFLAMMATION IN STOMACH
AND DUODENUM CONCERNING
FOR GASTRITIS, SO PT WAS
STARTED ON PANTOPRAZOLE
40MG DAILY. NAUSEA AND
VOMITING RESOLVED WITH
ABILITY TO TOLERATE BLAND
PO DIET.

PT BEGAN HAVING RIGHT
SIDED HEADACHE WITH
RHINORRHEA, PAIN WITH
EXTRAOCULAR MOVEMENTS,
BLURRY VISION, MILD

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

ERYTHEMA AND EDEMA. PT WAS SEEN BY ENT AND OPHTHAMOLOGY WHO WERE CONCERNED FOR THE POSSIBILITY OF PRESEPTAL SINUSITIS. PT WAS STARTED ON PO MOXIFLOXAIN. CT OF SINUSES WITH CONTRAST AND CT NECK WITH CONTRAST DEMONSTRATED PRESEPTAL ORBITAL CELLULITIS. PT WAS DISCHARGED WITH OUTPATIENT ENT FOLLOW UP, IN ADDITION TO TEN DAY COURSE OF PO ANTIBIOTICS.

ID EVALUATED PATIENT ON 30SEP2020. PLAN WAS TO FINISH MOXIFLOXACIN 400MG DAILY FOR TOTAL OF TEN DAYS (FINISH ON 08OCT2020), ALONG WITH VANCOMYCIN 125 MG BID (FINISH ON 11OCT2020) FOR C DIFFICILE PROPHYLAXIS. PT WAS GIVEN COMPAZINE AND OMEPRAZOLE AT DISCHARGE.

DISCHARGED TO HOME ON 30SEP2020.

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

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

AEID	USA-US215-2020-MRNA-1273-P30 1000007
Adverse event	COVID-19 INFECTION
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☒ No ☐
Start date (dd MMM yyyy)	06 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	25 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

291 of 4253

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☒ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PER SUBJECT REPORT AT SCREENING SUBJECT REPORTS LIVING IN AN APARTMENT WITH TWO ESSENTIAL WORKERS, AND HAS NOT CHANGED LIFESTYLE AND IS NOT SHELTERING IN PLACE.

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

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)	0

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

AEID	USA-US215-2020-MRNA-1273-P30 1000004
Adverse event	PERICARDITIS
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	31 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	03 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	31 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	03 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

294 of 4253

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

PATIENT EXPERIENCED CHEST PAIN AND DIFFICULTY BREATHING ON 31 OCT 2020. WENT TO ED AND WAS ADMITTED WITH A DIAGNOSIS OF PERICARDITIS. SHE HAD AN UNCOMPLICATED COURSE AND WAS DISCHARGED ON 03 NOV 2020. PATIENT WAS ADMINISTERED 90 DAY COURSE OF COLCHICINE. FURTHER INFORMATION CAN BE PROVIDED ONCE MEDICAL RECORDS ARE OBTAINED.

PER MEDICAL RECORD REVIEW, SUBJECT EXPERIENCED CHEST PAIN 31OCT2020. WAS ADMITTED TO HOSPITAL AND DIAGNOSED WITH A SMALL TO MEDIUM SIZED LOCULATED PERICARDIAL EFFUSION, NOTED ON CT. SUBJECT WAS STARTED ON FONDAPARINUX, ANTICOAGULANT SUBJECT HAD NEGATIVE CARDIAC WORK UP, INCLUDING NUCLEAR STRESS TEST. SUBJECT WAS STARTED ON A THREE MONTH COURSE OF COLCHICINE FOR POSSIBLE PERICARDITIS, PER CARDIOLOGY CONSULT. SUBJECT WAS DISCHARGED ON 03NOV2020. HAS SINCE BEEN SEEN AT SITE FEELING WELL AND ASYMPTOMATIC.

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

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

AEID

Adverse event

ELEVATED BLOOD PRESSURE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

297 of 4253

EAB) (1725)

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☒ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

AEID

Adverse event

LYMPHADENOPATHY

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

299 of 4253

EAB) (1725)

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 16 Apr 2021 16:31:30

Generated On: 10 Jun 2021 10:33:44

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 16:31:33

Generated On: 10 Jun 2021 10:33:44

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

Yes ☒

No ☐

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

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication PAXIL

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

302 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1996
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 03 OCT 2020		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ARIXTRA

Prophylaxis Yes ☐
No ☒

Indication ANTIPHOSPHOLIPID
SYNDROME

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

304 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2011
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication NORCO

Prophylaxis Yes ☐
No ☒

Indication CHRONIC PAIN SYNDROME

Dose per administration 10/325

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

306 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK	2014
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC PAIN SYNDROME

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

308 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ACYCLOVIR

Prophylaxis Yes ☐
No ☒

Indication HERPES SIMPLEX I

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

310 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 14 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication TYLENOL [ACETAMINOPHEN]

Prophylaxis Yes ☐
No ☒

Indication 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

312 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 12 SEP 2020		
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication COLCHICINE

Prophylaxis Yes ☐
No ☒

Indication 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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

314 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication TYLENOL EXTRA STRENGTH
[ACETAMINOPHEN]

Prophylaxis Yes ☐
No ☒

Indication COVID-19 POSITIVE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

316 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	06 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	13 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 200

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

If dose unit is Other, specify ML/HR

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 CONTINUOUS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

318 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		01 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 50

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

If dose unit is Other, specify ML/HR

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 CONTINUOUS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

320 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 02 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ZOFRAN

Prophylaxis Yes ☒
No ☐

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

322 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC PAIN SYNDROME

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

324 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication PROTONIX

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

326 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	03 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication PROTONIX [PANTOPRAZOLE SODIUM]

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

328 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		01 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 40

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

If dose unit is Other, specify MEQ/L

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

If frequency is Other, specify EVERY FOUR HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

330 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 02 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication NORCO

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 15/650

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

PRN Q4HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

332 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 03 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ATIVAN

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 2

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

PRN Q4HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

334 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 02 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 2

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)

336 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		01 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 31 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

340 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	31 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication FONDAPARINUX

Prophylaxis Yes ☒
No ☐

Indication DEEP VEIN THROMBOSIS

Dose per administration 0.8

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)

342 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 31 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 650

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)

344 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication KLONOPIN

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	02 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication FLUOXETINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 03 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication RHEUMATOID ARTHRITIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	17 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication MYALGIA

Dose per administration 650

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)

352 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 12 SEP 2020		
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication PAROXETINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication FLUOXETINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication CLONAZEPAM

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication MELATONIN

Prophylaxis Yes ☒
No ☐

Indication INSOMNIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

364 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ABATACEPT

Prophylaxis Yes ☐
No ☒

Indication RHEUMATOID ARTHRITIS

Dose per administration 125

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

If dose unit is Other, specify MG/ML

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)

366 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 JUN 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☒
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 100

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)

368 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	05 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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

If dose unit is Other, specify MCG

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)

370 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☒
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication LACTOBACILLUS
ACIDOPHILUS

Prophylaxis Yes ☒
No ☐

Indication PROPHYLACTIC

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

372 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	06 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	05 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication BARIUM SULFATE ORAL
SUSPENSION 2%

Prophylaxis Yes ☐
No ☒

Indication IMAGING (BARIUM SWALLOW)

Dose per administration 450

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	05 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		03 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication MOXIFLAXACIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS

Dose per administration 400

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)

376 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	08 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication COMPAZINE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

378 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 30 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication C DIFF

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

380 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q12HRS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

382 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 11 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication MELATONIN

Prophylaxis Yes ☒
No ☐

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

384 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

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

Q6HRS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

386 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		30 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication COMPAZINE

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

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

Q4HR

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

388 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		30 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

390 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication MOXIFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS

Dose per administration 400

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)

392 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 30 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication FONDAPARINUX

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS DVT

Dose per administration 10/0.3

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

If dose unit is Other, specify MG/ML

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)

394 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication AFRIN NASAL SPRAY 0.05%

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

396 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☒
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN SECONDARY TO
GASTRITIS

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

TID PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

398 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		30 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FLUIDS

Dose per administration 100/1000

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

If dose unit is Other, specify ML/MG

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 CONTINUOUS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

400 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		30 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

Dose per administration 8

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)

402 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 23 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication PROCHLORPERAZINE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

Dose per administration 5

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

If dose unit is Other, specify MG/ML

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)

404 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 26 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication PLASMA LYTE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

406 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 23 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

Dose per administration 1000/100

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

If dose unit is Other, specify MG/ML

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)

408 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 23 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ☒
Indication	GASTRITIS
Dose per administration	4/1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MG/ML
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)

410 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 24 SEP 2020		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

Dose per administration 4/2

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

If dose unit is Other, specify MG/ML

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)

412 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	27 SEP 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication PROCHLORPERAZINE

Prophylaxis Yes ☐
No ☒

Indication NAUSEA SECONDARY TO
GASTRITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

414 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ☒
Indication	PAIN SECONDARY TO GASTRITIS
Dose per administration	4/1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MG/ML
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

416 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	24 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication PROCHLORPERAZINE

Prophylaxis Yes ☐
No ☒

Indication NAUSEA SECONDARY TO
GASTRITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

418 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	25 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN SECONDARY TO
GASTRITIS

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

420 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

422 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 24 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication ANTIBIOTIC

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

424 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 25 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

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

Q8HR

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

426 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 25 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication CIPROFLOXACIN + D5W

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

Dose per administration 400/200

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

If dose unit is Other, specify MG/ML

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 Q12HRS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

428 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 25 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

430 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 25 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ☒
Indication	PAIN SECONDARY TO GASTRITIS
Dose per administration	2/1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MG/ML
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☒ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

432 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	27 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA SECONDARY TO
GASTRITIS

Dose per administration 4/2

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

434 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	26 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN SECONDARY TO
GASTRITIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

436 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication D5W (DEXTROSE 5% WATER)
NACL 0.45% IV FLUID

Prophylaxis Yes ☒
No ☐

Indication FLUIDS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

438 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	26 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication NAUSEA SECONDARY TO
GASTRITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

440 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ☒
Indication	PAIN SECONDARY TO GASTRITIS
Dose per administration	4/1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MG/ML
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	Q8HR PRN
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

442 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	27 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN SECONDARY GASTRITIS

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

BID PRN

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

444 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

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

Generated On: 10 Jun 2021 10:33:44

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 29 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

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

Generated On: 10 Jun 2021 10:33:44

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN SECONDARY TO
GASTRITIS

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

TID PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

446 of 4253

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

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

Generated On: 10 Jun 2021 10:33:44

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		30 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 21:10:05

Generated On: 10 Jun 2021 10:33:44

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 07 Apr 2021 21:10:05

Generated On: 10 Jun 2021 10:33:44

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 OCT 2020	CTA PE PROTOCOL W WO IV CONTRAST FOR PERICARDITIS	Adverse Event	
01 NOV 2020	PHARMACOLOGICAL NUCLEAR CARDIAC STRESS TEST FOR PERICARDITIS	Adverse Event	
02 NOV 2020	TRANSTHORACIC ECHO REPORT (2D WITH DOPPLER AND COLOR FLOW)	Adverse Event	
01 NOV 2020	MRI OF THE BRAIN WITHOUT CONTRAST FOR PERICARDITIS	Adverse Event	
01 NOV 2020	CT OF THE SINUS WITHOUT CONTRAST FOR PERICARDITIS	Adverse Event	
01 NOV 2020	CT OF THE HEAD WITHOUT CONTRAST FOR PERICARDITIS	Adverse Event	
31 OCT 2020	12 LEAD EKG FOR PERICARDITIS	Adverse Event	
28 SEP 2020	ESOPHAGOGASTRODUODENOSC OPY FOR GASTRITIS	Adverse Event	

US3952033

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

Date of dosing discontinuation (dd MMM yyyy) 08 OCT 2020

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

US3952033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 19 Apr 2021 20:52:19

Generated On: 10 Jun 2021 10:33:44

Date of study discontinuation/completion (dd MMM yyyy) 20 JAN 2021

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 NOT MEDICALLY STABLE TO PROCEED TO OPEN LABEL VACCINE. WILL GET OUTSIDE EUA LEADING TO WITHDRAW.

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	☐

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/SEP/2020 10:21
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

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/OCT/2020 14:22
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

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/OCT/2020 14:50
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

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/NOV/2020 10:36
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

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	03/DEC/2020 14:24
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

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/JAN/2021 15:20
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

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/FEB/2021 10:48
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

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	05/NOV/2020 17:03
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

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/NOV/2020 09:29
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

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/NOV/2020 21:17
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

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000007
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000007
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	03/DEC/2020 14:20
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

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 07 Apr 2021 21:10:08

Generated On: 10 Jun 2021 10:33:44

SAEID	USA-US215-2020-MRNA-1273-P301000007
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	22/DEC/2020 09:30
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

US3952033 (Prod: Synexus - Optimal Research - Rockville)

US3952033

Form: Participant Creation

Generated On: 10 Jun 2021 10:33:44

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:24:15
User entered 'US3952033'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:19:44

US3952033

Form: Participant Creation

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:07:38
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 15:38:32

US3952033

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:07:38
	(b) (4), (b) (6)	
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:19:45

US3952033

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:07:38
User entered 'Clinic (Clinic)'	Nick Bart (b) (4)	16 Sep 2020 15:38:32

US3952033

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'SCRN'	System	16 Sep 2020 15:38:32

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:11:33
User closed query 'Per CDM: Only 'Date of Birth' is recorded, however remaining details are missing in Demographics form. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 09:55:13
Query 'Per CDM: Only 'Date of Birth' is recorded, however remaining details are missing in Demographics form. Please review and update as appropriate. Thank you. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	16 Sep 2020 15:47:37
User opened query 'Per CDM: Only 'Date of Birth' is recorded, however remaining details are missing in Demographics form. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 12:15:14
User entered (b) (6) 1968'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:19:46

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:11:33
User entered '52'	Nick Bart (b) (4)	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered 'YEARS'	System	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '52'	System	02 Sep 2020 21:07:17

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:33
	(b) (4), (b) (6)	
User entered 'Female (F)'	Nick Bart (b) (4)	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:11:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Nick Bart (b) (4)	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:33
	(b) (4), (b) (6)	
User entered '1'	Nick Bart (b) (4)	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:11:33
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:33
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:33
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:33
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:11:33
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:11:33
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:33
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:33:44

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:11:33
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:07:25

US3952033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:33:44

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:58
	(b) (4), (b) (6)	
User entered '02 Sep 2020'	Atanas Filev (b) (4)	02 Sep 2020 21:07:17
	(b) (4)	

US3952033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:33:44

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Sep 2020'	System	02 Sep 2020 21:07:17

US3952033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:33:44

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2020'	System	02 Sep 2020 21:07:17

US3952033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:33:44

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:58
	(b) (4), (b) (6)	
User entered 'Amendment 2 (2)'	Atanas Filev (b) (4)	02 Sep 2020 21:07:17
	(b) (4)	

US3952033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:33:44

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:58
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Atanas Filev (b) (4)	02 Sep 2020 21:07:17
	(b) (4)	

US3952033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:33:44

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:58
	(b) (4), (b) (6)	
User entered empty.	Atanas Filev (b) (4)	02 Sep 2020 21:07:17
	(b) (4)	

US3952033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:33:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:58
	(b) (4), (b) (6)	
User entered empty.	Atanas Filev (b) (4)	02 Sep 2020 21:07:17
	(b) (4)	

US3952033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:33:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:58
	(b) (4), (b) (6)	
User entered 'No (N)'	Atanas Filev (b) (4)	02 Sep 2020 21:07:17
	(b) (4)	

US3952033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:33:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:11:58
	(b) (4), (b) (6)	
User entered empty.	RWS_ENDPOINT	02 Sep 2020 18:19:45
	ENDPOINT (b) (4)	

US3952033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:33:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '1'	System	02 Sep 2020 21:07:21

US3952033

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:33:44

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:14:07
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	02 Sep 2020 21:07:21

US3952033

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:33:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:14:12
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 15:47:44

US3952033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:49:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:49:36
Data point term sent to Coder	System	16 Sep 2020 15:48:44
User entered 'chronic sinusitis'	Nick Bart (b) (4)	16 Sep 2020 15:48:42

US3952033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 1992'	Nick Bart (b) (4)	16 Sep 2020 15:48:42

US3952033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:48:42

US3952033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 15:48:42

US3952033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 15:48:42

US3952033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:48:42

US3952033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 1992'	System	16 Sep 2020 15:48:42

US3952033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '1992'	System	16 Sep 2020 15:48:42

US3952033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:48:42

US3952033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:48:42

US3952033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Coagulopathies and bleeding diatheses (excl thrombocytopenic), HLT: Coagulopathies, PT: Antiphospholipid syndrome, LLT: Antiphospholipid syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:50:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:50:39
Data point term sent to Coder	System	16 Sep 2020 15:49:47
User entered 'Antiphospholipid syndrome'	Nick Bart (b) (4)	16 Sep 2020 15:49:21

US3952033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 2011'	Nick Bart (b) (4)	16 Sep 2020 15:49:21

US3952033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:49:21

US3952033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 15:49:21

US3952033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 15:49:21

US3952033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:49:21

US3952033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2011'	System	16 Sep 2020 15:49:21

US3952033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2011'	System	16 Sep 2020 15:49:21

US3952033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:49:21

US3952033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:49:21

US3952033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
User closed query 'Per DM CLR: Re-Query: Response noted. However, kindly report the concomitant medication for this condition else provide an explanation for no medical treatment. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:32:08
Query 'Per DM CLR: Re-Query: Response noted. However, kindly report the concomitant medication for this condition else provide an explanation for no medical treatment. Please review and update as appropriate. Thank you.' answered with 'no medical treatment. subject did not provide any further information.' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 19:52:24
User opened query 'Per DM CLR: Re-Query: Response noted. However, kindly report the concomitant medication for this condition else provide an explanation for no medical treatment. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:13:58
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:13:58
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Correct as entered' (Site from DM).	Nick Bart (b) (4)	02 Nov 2020 21:28:31
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:25:05

US3952033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:18:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 15:50:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	16 Sep 2020 15:50:39
Data point term sent to Coder	System	16 Sep 2020 15:49:48
User entered 'rheumatoid arthritis'	Nick Bart (b) (4)	16 Sep 2020 15:49:38

US3952033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 2006'	Nick Bart (b) (4)	16 Sep 2020 15:49:38

US3952033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:49:38

US3952033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 15:49:38

US3952033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 15:49:38

US3952033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:49:38

US3952033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2006'	System	16 Sep 2020 15:49:38

US3952033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2006'	System	16 Sep 2020 15:49:38

US3952033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:49:38

US3952033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:49:38

US3952033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:51:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:51:35
Data point term sent to Coder	System	16 Sep 2020 15:50:48
User entered 'osteoarthritis'	Nick Bart (b) (4)	16 Sep 2020 15:49:51

US3952033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 1995'	Nick Bart (b) (4)	16 Sep 2020 15:49:51

US3952033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:49:51

US3952033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 15:49:51

US3952033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 15:49:51

US3952033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:49:51

US3952033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 1995'	System	16 Sep 2020 15:49:51

US3952033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '1995'	System	16 Sep 2020 15:49:51

US3952033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:49:51

US3952033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:49:51

US3952033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:33:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Chronic pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:51:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:51:35
Data point term sent to Coder	System	16 Sep 2020 15:50:48
User entered 'chronic pain syndrome'	Nick Bart (b) (4)	16 Sep 2020 15:50:05

US3952033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 2014'	Nick Bart (b) (4)	16 Sep 2020 15:50:05

US3952033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:50:05

US3952033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 15:50:05

US3952033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 15:50:05

US3952033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:50:05

US3952033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2014'	System	16 Sep 2020 15:50:05

US3952033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2014'	System	16 Sep 2020 15:50:05

US3952033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:50:05

US3952033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:50:05

US3952033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:33:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User coded data point as SOC: Psychiatric disorders, HLTG: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:51:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:51:35
Data point term sent to Coder	System	16 Sep 2020 15:50:48
User entered 'anxiety'	Nick Bart (b) (4)	16 Sep 2020 15:50:15

US3952033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 2010'	Nick Bart (b) (4)	16 Sep 2020 15:50:15

US3952033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:50:15

US3952033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 15:50:15

US3952033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 15:50:15

US3952033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:50:15

US3952033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2010'	System	16 Sep 2020 15:50:15

US3952033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2010'	System	16 Sep 2020 15:50:15

US3952033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:50:15

US3952033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:50:15

US3952033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:51:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:51:36
Data point term sent to Coder	System	16 Sep 2020 15:50:49
User entered 'depression'	Nick Bart (b) (4)	16 Sep 2020 15:50:28

US3952033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'un UNK 1996'	Nick Bart (b) (4)	16 Sep 2020 15:50:28

US3952033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:50:28

US3952033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 15:50:28

US3952033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 15:50:28

US3952033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:50:28

US3952033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 1996'	System	16 Sep 2020 15:50:28

US3952033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '1996'	System	16 Sep 2020 15:50:28

US3952033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:50:28

US3952033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:50:28

US3952033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis flare up - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 07:54:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 07:54:45
Data point term sent to Coder	System	16 Sep 2020 15:51:50
User entered 'Rhuematoid Arthritis Flare'	Nick Bart (b) (4)	16 Sep 2020 15:51:14

US3952033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un Mar 2020'	Nick Bart (b) (4)	16 Sep 2020 15:51:14

US3952033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:51:14

US3952033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 15:51:14

US3952033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un Apr 2020'	Nick Bart (b) (4)	16 Sep 2020 15:51:14

US3952033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:51:14

US3952033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Mar 2020'	System	16 Sep 2020 15:51:14

US3952033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2020'	System	16 Sep 2020 15:51:14

US3952033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Apr 2020'	System	16 Sep 2020 15:51:14

US3952033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2020'	System	16 Sep 2020 15:51:14

US3952033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 07:32:46
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	03 Nov 2020 16:29:01
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:25:05
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:18:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:53:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:53:43
Data point term sent to Coder	System	16 Sep 2020 15:52:51
User entered 'hysterectomy'	Nick Bart (b) (4)	16 Sep 2020 15:52:47

US3952033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'un UNK 2009'	Nick Bart (b) (4)	16 Sep 2020 15:52:47

US3952033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:52:47

US3952033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 15:52:47

US3952033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 2009'	Nick Bart (b) (4)	16 Sep 2020 15:52:47

US3952033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:52:47

US3952033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2009'	System	16 Sep 2020 15:52:47

US3952033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2009'	System	16 Sep 2020 15:52:47

US3952033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2009'	System	16 Sep 2020 15:52:47

US3952033

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2009'	System	16 Sep 2020 15:52:47

US3952033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee arthroplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:54:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:54:39
Data point term sent to Coder	System	16 Sep 2020 15:53:52
User entered 'right Total Knee Arthroplasty'	Nick Bart (b) (4)	16 Sep 2020 15:53:24

US3952033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'un UNK 2011'	Nick Bart (b) (4)	16 Sep 2020 15:53:24

US3952033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:53:24

US3952033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 15:53:24

US3952033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 2011'	Nick Bart (b) (4)	16 Sep 2020 15:53:24

US3952033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:53:24

US3952033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2011'	System	16 Sep 2020 15:53:24

US3952033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2011'	System	16 Sep 2020 15:53:24

US3952033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2011'	System	16 Sep 2020 15:53:24

US3952033

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2011'	System	16 Sep 2020 15:53:24

US3952033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee arthroplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:54:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:54:38
Data point term sent to Coder	System	16 Sep 2020 15:53:53
User entered 'left Total Knee Arthroplasty'	Nick Bart (b) (4)	16 Sep 2020 15:53:46

US3952033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 2015'	Nick Bart (b) (4)	16 Sep 2020 15:53:46

US3952033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:53:46

US3952033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 15:53:46

US3952033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 2015'	Nick Bart (b) (4)	16 Sep 2020 15:53:46

US3952033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:53:46

US3952033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2015'	System	16 Sep 2020 15:53:46

US3952033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2015'	System	16 Sep 2020 15:53:46

US3952033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2015'	System	16 Sep 2020 15:53:46

US3952033

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2015'	System	16 Sep 2020 15:53:46

US3952033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ankle arthroplasty, LLT: Ankle reconstruction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:55:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:55:37
Data point term sent to Coder	System	16 Sep 2020 15:54:53
User entered 'left ankle reconstruction'	Nick Bart (b) (4)	16 Sep 2020 15:54:05

US3952033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'un UNK 2000'	Nick Bart (b) (4)	16 Sep 2020 15:54:05

US3952033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:54:05

US3952033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 15:54:05

US3952033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 2000'	Nick Bart (b) (4)	16 Sep 2020 15:54:05

US3952033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:54:05

US3952033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2000'	System	16 Sep 2020 15:54:05

US3952033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2000'	System	16 Sep 2020 15:54:05

US3952033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2000'	System	16 Sep 2020 15:54:05

US3952033

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2000'	System	16 Sep 2020 15:54:05

US3952033

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:55:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:55:36
Data point term sent to Coder	System	16 Sep 2020 15:54:56
User entered 'severe obesity'	Nick Bart (b) (4)	16 Sep 2020 15:54:17

US3952033

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 2005'	Nick Bart (b) (4)	16 Sep 2020 15:54:17

US3952033

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:54:17

US3952033

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 15:54:17

US3952033

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 15:54:17

US3952033

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 15:54:17

US3952033

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2005'	System	16 Sep 2020 15:54:17

US3952033

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2005'	System	16 Sep 2020 15:54:17

US3952033

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:54:17

US3952033

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 15:54:17

US3952033

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type I - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 16:06:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 16:06:41
Data point term sent to Coder	System	16 Sep 2020 16:06:17
User entered 'herpes simplex i'	Nick Bart (b) (4)	16 Sep 2020 16:05:32

US3952033

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:25:05
	(b) (4), (b) (6)	
User entered 'un UNK 1976'	Nick Bart (b) (4)	16 Sep 2020 16:05:32

US3952033

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:05:32

US3952033

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:05:32

US3952033

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:05:32

US3952033

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:25:05
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:05:32

US3952033

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 1976'	System	16 Sep 2020 16:05:32

US3952033

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '1976'	System	16 Sep 2020 16:05:32

US3952033

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 16:05:32

US3952033

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 16:05:32

US3952033

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:33:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:10:10
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:31:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:31:21
Data point term sent to Coder	System	03 Nov 2020 16:30:37
User entered 'uterine fibroids'	Nick Bart (b) (4)	03 Nov 2020 16:30:08

US3952033

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	06 Apr 2021 22:10:12
	(b) (4), (b) (6)	
User entered 'un UNK 2009'	Nick Bart (b) (4)	03 Nov 2020 16:30:08

US3952033

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	06 Apr 2021 22:10:14
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	03 Nov 2020 16:30:08

US3952033

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:33:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:10:15
User entered 'No (N)'	Nick Bart (b) (4)	03 Nov 2020 16:30:08

US3952033

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:33:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	06 Apr 2021 22:10:17
	(b) (4), (b) (6)	
User entered 'un UNK 2009'	Nick Bart (b) (4)	03 Nov 2020 16:30:08

US3952033

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:33:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	06 Apr 2021 22:10:18
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	03 Nov 2020 16:30:08

US3952033

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:33:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2009'	System	03 Nov 2020 16:30:08

US3952033

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:33:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2009'	System	03 Nov 2020 16:30:08

US3952033

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:33:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'Jan 2009'	System	03 Nov 2020 16:30:08

US3952033

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:33:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '2009'	System	03 Nov 2020 16:30:08

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:28:08
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:28:07
User entered '02 Sep 2020'	Nick Bart (b) (4)	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:28:05
User entered '13:52'	Nick Bart (b) (4)	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '02 Sep 2020 13:52'	System	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:28:02
User entered '65.0' in	Nick Bart (b) (4)	16 Sep 2020 16:10:37
DataPoint set to visible.	System	02 Sep 2020 21:07:21

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:28:01
User entered '293.0' lb	Nick Bart (b) (4)	16 Sep 2020 16:10:37
DataPoint set to visible.	System	02 Sep 2020 21:07:21

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
Query 'Per CDM: Per protocol BMI > 40 kg/m2 is at risk, yet participant is not recorded as at risk. Please review and reconcile or provide clarification.'	(b) (4), (b) (6)	25 Sep 2020 10:10:59
canceled (Site from DM).		
User opened query 'Per CDM: Per protocol BMI > 40 kg/m2 is at risk, yet participant is not recorded as at risk. Please review and reconcile or provide clarification.'	(b) (4), (b) (6)	25 Sep 2020 09:14:29
(Site from DM).		
User entered '48.85970'	System	16 Sep 2020 16:10:37
DataPoint set to visible.	System	02 Sep 2020 21:07:21

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'kg/m2'	System	16 Sep 2020 16:10:37
DataPoint set to visible.	System	02 Sep 2020 21:07:21

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:10:40
User closed query 'Per CDM: Per CCGs pages 15 &16 it states that if Screening and Visit 1 Day 1 were performed on the same day, then ND (Not done) should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF to avoid duplication of data. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:44:44
Query 'Per CDM: Per CCGs pages 15 &16 it states that if Screening and Visit 1 Day 1 were performed on the same day, then ND (Not done) should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF to avoid duplication of data. Please update accordingly. Thank you.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	03 Nov 2020 16:17:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:17:35
User opened query 'Per CDM: Per CCGs pages 15 &16 it states that if Screening and Visit 1 Day 1 were performed on the same day, then ND (Not done) should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF to avoid duplication of data. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:04:21
User entered '37.3' C	Nick Bart (b) (4)	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:10:40
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:17:35
User entered 'Oral (Oral)'	Nick Bart (b) (4)	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:10:40
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:10:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:17:35
User entered '65'	Nick Bart (b) (4)	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'bpm'	System	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:10:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:17:35
User entered '12'	Nick Bart (b) (4)	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'breaths/min'	System	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:10:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:17:35
User entered '150'	Nick Bart (b) (4)	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'mmHg'	System	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:10:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:17:35
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 09:56:31
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Nick Bart (b) (4)	16 Sep 2020 16:10:47
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Sep 2020 16:10:37
User entered '103'	Nick Bart (b) (4)	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'mmHg'	System	16 Sep 2020 16:10:37

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15

US3952033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15

US3952033

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:33:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:28:21
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:14:18

US3952033

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:33:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:28:21
	(b) (4), (b) (6)	
User entered '02 Sep 2020'	Nick Bart (b) (4)	16 Sep 2020 16:14:18

US3952033

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:33:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:28:36
User entered '02 Sep 2020'	Nick Bart (b) (4)	16 Sep 2020 16:24:43

US3952033

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:33:44

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:28:36
	(b) (4), (b) (6)	
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:24:43

US3952033

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:33:44

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:28:36
User entered 'Surgically sterile (SURGICALLY STERILE)'	Nick Bart (b) (4)	16 Sep 2020 16:24:43

US3952033

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:33:44

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:28:36
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:24:43

US3952033

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:33:44

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:28:36
User entered 'un UNK 2009'	Nick Bart (b) (4)	16 Sep 2020 16:24:43

US3952033

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:33:44

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:28:36
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:24:43

US3952033

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:33:44

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:28:36
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:24:43

US3952033

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:33:44

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:28:36
	(b) (4), (b) (6)	
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:24:43

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

[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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

[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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

[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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

[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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

[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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
User entered '0'	(b) (4) Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

[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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered '1'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:31:55
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
User entered '1'	(b) (4)	16 Sep 2020 16:08:32
	Nick Bart (b) (4)	

US3952033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:33:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:31:55
	(b) (4), (b) (6)	
User entered 'lives with two essential workers, no lifestyle change i.e. not sheltering in place.'	Nick Bart (b) (4)	16 Sep 2020 16:08:32

US3952033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:36:24
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:24:57

US3952033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:36:24
	(b) (4), (b) (6)	
User entered '02 Sep 2020'	Nick Bart (b) (4)	16 Sep 2020 16:24:57

US3952033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:36:24
User entered 'Clinic (Clinic)'	Nick Bart (b) (4)	16 Sep 2020 16:24:57

US3952033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'VISIT1'	System	16 Sep 2020 16:24:57

US3952033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:36:36
	(b) (4), (b) (6)	
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:14:38

US3952033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:33:44

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:36:36
	(b) (4), (b) (6)	
User entered '145311'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:14:38

US3952033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:33:44

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:36:36
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:14:38

US3952033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:33:44

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 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:36:36
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 09:55:35
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:27:13
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	16 Sep 2020 16:25:06
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 13:36:12

US3952033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:33:44

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 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:36:36
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:27:13

US3952033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:33:44

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:36:36
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:27:13

US3952033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:33:44

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:36:36
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:27:13

US3952033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:33:44

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:36:36
	(b) (4), (b) (6)	
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:27:13

US3952033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:33:44

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:36:36
User entered 'No (N)'	Nick Bart (b) (4)	02 Oct 2020 14:08:14
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:05:25
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:57:26

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:33:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:06:40
User closed query 'Per CDM: Per CCGs pages 15 &16 it states that if Screening and Visit 1 Day 1 were performed on the same day, then ND (Not done) should be recorded for HEIGHT and WEIGHT on Visit 1 Day 1 page to avoid duplication of data. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:44:07
Query 'Per CDM: Per CCGs pages 15 &16 it states that if Screening and Visit 1 Day 1 were performed on the same day, then ND (Not done) should be recorded for HEIGHT and WEIGHT on Visit 1 Day 1 page to avoid duplication of data. Please update accordingly. Thank you.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	03 Nov 2020 16:21:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User opened query 'Per CDM: Per CCGs pages 15 &16 it states that if Screening and Visit 1 Day 1 were performed on the same day, then ND (Not done) should be recorded for HEIGHT and WEIGHT on Visit 1 Day 1 page to avoid duplication of data. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:04:46
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:33:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:06:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:33:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:06:40
User closed query 'Per CDM: Per CCGs pages 15 &16 it states that if Screening and Visit 1 Day 1 were performed on the same day, then ND (Not done) should be recorded for HEIGHT and WEIGHT on Visit 1 Day 1 page to avoid duplication of data. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:44:07
Query 'Per CDM: Per CCGs pages 15 &16 it states that if Screening and Visit 1 Day 1 were performed on the same day, then ND (Not done) should be recorded for HEIGHT and WEIGHT on Visit 1 Day 1 page to avoid duplication of data. Please update accordingly. Thank you.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	03 Nov 2020 16:21:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User opened query 'Per CDM: Per CCGs pages 15 &16 it states that if Screening and Visit 1 Day 1 were performed on the same day, then ND (Not done) should be recorded for HEIGHT and WEIGHT on Visit 1 Day 1 page to avoid duplication of data. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:04:46
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:33:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:06:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:06:47
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Pre-Dose Vital Signs should be recorded at Visit 1 Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:46:00
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Pre-Dose Vital Signs should be recorded at Visit 1 Day 1. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	03 Nov 2020 16:21:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Pre-Dose Vital Signs should be recorded at Visit 1 Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 15:29:50
Data hard unlocked.	(b) (4), (b) (6)	25 Sep 2020 15:29:26
Data hard locked.	(b) (4), (b) (6)	25 Sep 2020 15:29:19
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:37
User entered '02 Sep 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:05
User entered '13:52' reason for change: Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '02 Sep 2020 13:52'	System	03 Nov 2020 16:21:12
User entered empty.	System	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:05
User entered '37.3' C reason for change: Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:05
User entered 'Oral (Oral)' reason for change: Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:05
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:05
User entered '65' reason for change: Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'bpm'	System	03 Nov 2020 16:21:12
User entered empty.	System	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:05
User entered '12' reason for change: Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'breaths/min'	System	03 Nov 2020 16:21:12
User entered empty.	System	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:05
User closed query 'Per CDM: Per CCG V2.0 page 53, SBP ≤ 89 or ≥ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:56:23
Query 'Per CDM: Per CCG V2.0 page 53, SBP ≤ 89 or ≥ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 17:07:04
User opened query 'Per CDM: Per CCG V2.0 page 53, SBP ≤ 89 or ≥ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:43:23
User entered '150' reason for change: Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'mmHg'	System	03 Nov 2020 16:21:12
User entered empty.	System	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:05
User closed query 'Per CDM: Per CCG V2.0 page 53, DBP $\geq$ 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:56:26
Query 'Per CDM: Per CCG V2.0 page 53, DBP $\geq$ 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 17:07:02
User opened query 'Per CDM: Per CCG V2.0 page 53, DBP $\geq$ 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:43:34
User entered '103' reason for change: Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'mmHg'	System	03 Nov 2020 16:21:12
User entered empty.	System	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:33:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:06:40
User closed query 'Per CDM: Per CCGs pages 15 &16 it states that if Screening and Visit 1 Day 1 were performed on the same day, then ND (Not done) should be recorded for HEIGHT and WEIGHT on Visit 1 Day 1 page to avoid duplication of data. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:44:07
Query 'Per CDM: Per CCGs pages 15 &16 it states that if Screening and Visit 1 Day 1 were performed on the same day, then ND (Not done) should be recorded for HEIGHT and WEIGHT on Visit 1 Day 1 page to avoid duplication of data. Please update accordingly. Thank you.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	03 Nov 2020 16:21:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User opened query 'Per CDM: Per CCGs pages 15 &16 it states that if Screening and Visit 1 Day 1 were performed on the same day, then ND (Not done) should be recorded for HEIGHT and WEIGHT on Visit 1 Day 1 page to avoid duplication of data. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:04:46
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:33:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:06:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	03 Nov 2020 16:21:12
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:47:17
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:47:19
User entered '02 Sep 2020'	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:47:21
User entered '16:57'	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '02 Sep 2020 16:57'	System	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:47:23
User entered '36.9' C	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:47:24
User entered 'Oral (Oral)'	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:47:26
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:47:28
User entered '69'	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'bpm'	System	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:47:32
User entered '14'	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'breaths/min'	System	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:47:36
	(b) (4), (b) (6)	
User entered '139'	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'mmHg'	System	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:05
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 20:47:42
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:47:38
User entered '90'	Nick Bart (b) (4)	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'mmHg'	System	16 Sep 2020 16:29:54

US3952033

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:33:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:45:07
	(b) (4), (b) (6)	
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:27:31

US3952033

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:33:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:45:07
	(b) (4), (b) (6)	
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:27:31

US3952033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:48:57
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Atanas Filev (b) (4)	02 Sep 2020 21:08:05
	(b) (4)	

US3952033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:48:57
	(b) (4), (b) (6)	
User entered empty.	Atanas Filev (b) (4)	02 Sep 2020 21:08:05
	(b) (4)	

US3952033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:48:57
User entered empty.	Atanas Filev (b) (4) (b) (4)	02 Sep 2020 21:08:05

US3952033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 21:08:05

US3952033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:48:57
	(b) (4), (b) (6)	
User entered '02 Sep 2020'	Atanas Filev (b) (4)	02 Sep 2020 21:08:05
	(b) (4)	

US3952033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:48:57
	(b) (4), (b) (6)	
User entered '16:09'	Atanas Filev (b) (4)	02 Sep 2020 21:08:05
	(b) (4)	

US3952033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '02 Sep 2020 16:09'	System	02 Sep 2020 21:08:05

US3952033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4)	30 Oct 2020 20:48:57
	(b) (4), (b) (6)	
User entered 'Left Arm (LEFT ARM)'	Atanas Filev (b) (4)	02 Sep 2020 21:08:05
	(b) (4)	

US3952033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:48:57
User entered 'ONCE'	System	02 Sep 2020 21:08:05

US3952033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 21:08:05

US3952033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:56
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:28:59

US3952033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:56
User entered '02 Sep 2020'	Nick Bart (b) (4)	16 Sep 2020 16:28:59

US3952033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:56
User entered '14:50'	Nick Bart (b) (4)	16 Sep 2020 16:28:59

US3952033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '02 Sep 2020 14:50'	System	16 Sep 2020 16:28:59

US3952033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:33:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:50:03
User entered '02 Sep 2020'	Nick Bart (b) (4)	16 Sep 2020 16:29:12

US3952033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:33:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4)	16 Sep 2020 16:29:12

US3952033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:33:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:50:03
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:29:12

US3952033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:33:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:50:03
User entered '14:36'	Nick Bart (b) (4)	16 Sep 2020 16:29:12

US3952033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:33:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '02 Sep 2020 14:36'	System	16 Sep 2020 16:29:12

US3952033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:33:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4)	16 Sep 2020 16:29:12

US3952033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:33:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:50:03
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:29:12

US3952033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:33:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:50:03
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:29:12

US3952033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:33:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	16 Sep 2020 16:29:12

US3952033

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:50:12
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:27:43

US3952033

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '1'	System	16 Sep 2020 16:27:43

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:08:38', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'dd9a7727-f857-46a3-8166-fb7f7a202d70'	System	02 Sep 2020 21:09:26
User entered 'Yes (Y)'	System	02 Sep 2020 21:09:26

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:09:04', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'dd9a7727-f857-46a3-8166-fb7f7a202d70'	System	02 Sep 2020 21:09:26
User entered '98.4'	System	02 Sep 2020 21:09:26

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:09:15', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'dd9a7727-f857-46a3-8166-fb7f7a202d70'	System	02 Sep 2020 21:09:26
User entered 'No (N)'	System	02 Sep 2020 21:09:26

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:09:22', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'dd9a7727-f857-46a3-8166-fb7f7a202d70'	System	02 Sep 2020 21:09:26
User entered '02 Sep 2020 17:09'	System	02 Sep 2020 21:09:26

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '02 Sep 2020 16:29'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '02 Sep 2020 18:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:04:01', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b2f81f6a-c6d8-4cc3-a707-f9c7b74c46d2'	System	03 Sep 2020 00:04:43
User entered 'Yes (Y)'	System	03 Sep 2020 00:04:43

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:04:08', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b2f81f6a-c6d8-4cc3-a707-f9c7b74c46d2'	System	03 Sep 2020 00:04:43
User entered '98.2'	System	03 Sep 2020 00:04:43

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:04:17', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b2f81f6a-c6d8-4cc3-a707-f9c7b74c46d2'	System	03 Sep 2020 00:04:43
User entered 'Yes (Y)'	System	03 Sep 2020 00:04:43

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:16:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:50:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:04:27', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b2f81f6a-c6d8-4cc3-a707-f9c7b74c46d2'	System	03 Sep 2020 00:04:43
User entered '1'	System	03 Sep 2020 00:04:43

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:04:27', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b2f81f6a-c6d8-4cc3-a707-f9c7b74c46d2'	System	03 Sep 2020 00:04:43
User entered '0'	System	03 Sep 2020 00:04:43

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:04:39', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b2f81f6a-c6d8-4cc3-a707-f9c7b74c46d2'	System	03 Sep 2020 00:04:43
User entered '02 Sep 2020 20:04'	System	03 Sep 2020 00:04:43

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '02 Sep 2020 19:54'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 2'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:43:37', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd74d3ff4-5b80-4f59-8a1c-1db6f7c096a6'	System	03 Sep 2020 21:44:57
User entered 'Yes (Y)'	System	03 Sep 2020 21:44:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:44:21', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd74d3ff4-5b80-4f59-8a1c-1db6f7c096a6'	System	03 Sep 2020 21:44:57
User entered '98.8'	System	03 Sep 2020 21:44:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:44:34', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd74d3ff4-5b80-4f59-8a1c-1db6f7c096a6'	System	03 Sep 2020 21:44:57
User entered 'Yes (Y)'	System	03 Sep 2020 21:44:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:16:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:50:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:44:44', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd74d3ff4-5b80-4f59-8a1c-1db6f7c096a6'	System	03 Sep 2020 21:44:57
User entered '1'	System	03 Sep 2020 21:44:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:44:44', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd74d3ff4-5b80-4f59-8a1c-1db6f7c096a6'	System	03 Sep 2020 21:44:57
User entered '0'	System	03 Sep 2020 21:44:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:44:53', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd74d3ff4-5b80-4f59-8a1c-1db6f7c096a6'	System	03 Sep 2020 21:44:57
User entered '03 Sep 2020 17:44'	System	03 Sep 2020 21:44:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 3'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:26:46', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '2c9715e0-e23e-418f-b386-b39e7674e5ee'	System	05 Sep 2020 01:27:17
User entered 'Yes (Y)'	System	05 Sep 2020 01:27:17

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:26:54', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '2c9715e0-e23e-418f-b386-b39e7674e5ee'	System	05 Sep 2020 01:27:17
User entered '98.5'	System	05 Sep 2020 01:27:17

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:26:59', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '2c9715e0-e23e-418f-b386-b39e7674e5ee'	System	05 Sep 2020 01:27:17
User entered 'Yes (Y)'	System	05 Sep 2020 01:27:17

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:27:07', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '2c9715e0-e23e-418f-b386-b39e7674e5ee'	System	05 Sep 2020 01:27:17
User entered '0'	System	05 Sep 2020 01:27:17

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:16:55
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:50:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:27:07', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '2c9715e0-e23e-418f-b386-b39e7674e5ee'	System	05 Sep 2020 01:27:17
User entered '1'	System	05 Sep 2020 01:27:17

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:27:15', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '2c9715e0-e23e-418f-b386-b39e7674e5ee'	System	05 Sep 2020 01:27:17
User entered '04 Sep 2020 21:27'	System	05 Sep 2020 01:27:17

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 4'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:43:49', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '09d4bbbf-7035-40e6-bfd9-d6d1176ae965'	System	06 Sep 2020 01:44:21
User entered 'Yes (Y)'	System	06 Sep 2020 01:44:21

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:43:55', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '09d4bbbf-7035-40e6-bfd9-d6d1176ae965'	System	06 Sep 2020 01:44:21
User entered '98.8'	System	06 Sep 2020 01:44:21

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:44:02', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '09d4bbbf-7035-40e6-bfd9-d6d1176ae965'	System	06 Sep 2020 01:44:21
User entered 'Yes (Y)'	System	06 Sep 2020 01:44:21

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:44:10', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '09d4bbbf-7035-40e6-bfd9-d6d1176ae965'	System	06 Sep 2020 01:44:21
User entered '0'	System	06 Sep 2020 01:44:21

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:17:02
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:50:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:44:10', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '09d4bbbf-7035-40e6-bfd9-d6d1176ae965'	System	06 Sep 2020 01:44:21
User entered '1'	System	06 Sep 2020 01:44:21

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:44:17', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '09d4bbbf-7035-40e6-bfd9-d6d1176ae965'	System	06 Sep 2020 01:44:21
User entered '05 Sep 2020 21:44'	System	06 Sep 2020 01:44:21

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 5'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:07:32', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'baa2f437-5d81-4623-a352-0c31c655426c'	System	07 Sep 2020 00:09:36
User entered 'Yes (Y)'	System	07 Sep 2020 00:09:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:07:42', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'baa2f437-5d81-4623-a352-0c31c655426c'	System	07 Sep 2020 00:09:36
User entered '97.8'	System	07 Sep 2020 00:09:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:07:49', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'baa2f437-5d81-4623-a352-0c31c655426c'	System	07 Sep 2020 00:09:36
User entered 'Yes (Y)'	System	07 Sep 2020 00:09:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:17:11
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:50:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:09:21', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'baa2f437-5d81-4623-a352-0c31c655426c'	System	07 Sep 2020 00:09:36
User entered '1'	System	07 Sep 2020 00:09:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:17:14
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:09:21', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'baa2f437-5d81-4623-a352-0c31c655426c'	Nick Bart (b) (4)	10 Nov 2020 20:51:00
User entered '1'	System	07 Sep 2020 00:09:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:09:32', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'baa2f437-5d81-4623-a352-0c31c655426c'	System	07 Sep 2020 00:09:36
User entered '06 Sep 2020 20:09'	System	07 Sep 2020 00:09:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 6'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:21:00', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'c22387c0-11bf-40a7-b6e5-f1ffd3d8d8d0'	System	07 Sep 2020 23:21:27
User entered 'Yes (Y)'	System	07 Sep 2020 23:21:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:21:07', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'c22387c0-11bf-40a7-b6e5-f1ffd3d8d8d0'	System	07 Sep 2020 23:21:27
User entered '98.0'	System	07 Sep 2020 23:21:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:21:13', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'c22387c0-11bf-40a7-b6e5-f1ffd3d8d8d0'	System	07 Sep 2020 23:21:27
User entered 'Yes (Y)'	System	07 Sep 2020 23:21:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:17:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:51:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:21:21', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'c22387c0-11bf-40a7-b6e5-f1ffd3d8d8d0'	System	07 Sep 2020 23:21:27
User entered '1'	System	07 Sep 2020 23:21:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:17:30
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:51:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:21:21', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'c22387c0-11bf-40a7-b6e5-f1ffd3d8d8d0'	System	07 Sep 2020 23:21:27
User entered '1'	System	07 Sep 2020 23:21:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:21:26', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'c22387c0-11bf-40a7-b6e5-f1ffd3d8d8d0'	System	07 Sep 2020 23:21:27
User entered '07 Sep 2020 19:21'	System	07 Sep 2020 23:21:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 7'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:37:04', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b94950c9-cced-4c51-90ec-d7ba76590d0c'	System	09 Sep 2020 00:37:36
User entered 'Yes (Y)'	System	09 Sep 2020 00:37:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:37:11', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b94950c9-cced-4c51-90ec-d7ba76590d0c'	System	09 Sep 2020 00:37:36
User entered '98.1'	System	09 Sep 2020 00:37:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:37:16', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b94950c9-cced-4c51-90ec-d7ba76590d0c'	System	09 Sep 2020 00:37:36
User entered 'Yes (Y)'	System	09 Sep 2020 00:37:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:17:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:51:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:37:23', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b94950c9-cced-4c51-90ec-d7ba76590d0c'	System	09 Sep 2020 00:37:36
User entered '1'	System	09 Sep 2020 00:37:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:17:38
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:51:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:37:23', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b94950c9-cced-4c51-90ec-d7ba76590d0c'	System	09 Sep 2020 00:37:36
User entered '1'	System	09 Sep 2020 00:37:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:37:29', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b94950c9-cced-4c51-90ec-d7ba76590d0c'	System	09 Sep 2020 00:37:36
User entered '08 Sep 2020 20:37'	System	09 Sep 2020 00:37:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	07 Sep 2020 23:21:27
User entered 'Day 8'	System	07 Sep 2020 23:21:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T19:58:49', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '70ad8ddc-9f1a-44c2-8e83-8699c8e8753e'	System	09 Sep 2020 23:59:31
User entered 'Yes (Y)'	System	09 Sep 2020 23:59:31

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T19:58:58', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '70ad8ddc-9f1a-44c2-8e83-8699c8e8753e'	System	09 Sep 2020 23:59:31
User entered '97.8'	System	09 Sep 2020 23:59:31

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T19:59:04', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '70ad8ddc-9f1a-44c2-8e83-8699c8e8753e'	System	09 Sep 2020 23:59:31
User entered 'Yes (Y)'	System	09 Sep 2020 23:59:31

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:17:44
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:51:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T19:59:13', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '70ad8ddc-9f1a-44c2-8e83-8699c8e8753e'	System	09 Sep 2020 23:59:31
User entered '1'	System	09 Sep 2020 23:59:31

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:17:46
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:51:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T19:59:13', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '70ad8ddc-9f1a-44c2-8e83-8699c8e8753e'	System	09 Sep 2020 23:59:31
User entered '1'	System	09 Sep 2020 23:59:31

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T19:59:25', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '70ad8ddc-9f1a-44c2-8e83-8699c8e8753e'	System	09 Sep 2020 23:59:31
User entered '09 Sep 2020 19:59'	System	09 Sep 2020 23:59:31

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 23:21:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 23:21:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	09 Sep 2020 00:37:36
User entered 'Day 9'	System	09 Sep 2020 00:37:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:25:23', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '4df0bff4-c8c4-423d-bc8d-e43dc361e21f'	System	11 Sep 2020 02:25:57
User entered 'Yes (Y)'	System	11 Sep 2020 02:25:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:25:33', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '4df0bff4-c8c4-423d-bc8d-e43dc361e21f'	System	11 Sep 2020 02:25:57
User entered '97.9'	System	11 Sep 2020 02:25:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:25:37', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '4df0bff4-c8c4-423d-bc8d-e43dc361e21f'	System	11 Sep 2020 02:25:57
User entered 'Yes (Y)'	System	11 Sep 2020 02:25:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:17:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:51:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:25:42', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '4df0bff4-c8c4-423d-bc8d-e43dc361e21f'	System	11 Sep 2020 02:25:57
User entered '1'	System	11 Sep 2020 02:25:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:17:54
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:51:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:25:42', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '4df0bff4-c8c4-423d-bc8d-e43dc361e21f'	System	11 Sep 2020 02:25:57
User entered '1'	System	11 Sep 2020 02:25:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:25:52', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '4df0bff4-c8c4-423d-bc8d-e43dc361e21f'	System	11 Sep 2020 02:25:57
User entered '10 Sep 2020 22:25'	System	11 Sep 2020 02:25:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 00:37:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 00:37:36

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	09 Sep 2020 23:59:31
User entered 'Day 10'	System	09 Sep 2020 23:59:31

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:36:55', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '56e7fd1e-b2e2-40a4-9a7c-0f69adf812ac'	System	12 Sep 2020 12:37:18
User entered 'Yes (Y)'	System	12 Sep 2020 12:37:18

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:37:02', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '56e7fd1e-b2e2-40a4-9a7c-0f69adf812ac'	System	12 Sep 2020 12:37:18
User entered '98.6'	System	12 Sep 2020 12:37:18

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:37:05', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '56e7fd1e-b2e2-40a4-9a7c-0f69adf812ac'	System	12 Sep 2020 12:37:18
User entered 'Yes (Y)'	System	12 Sep 2020 12:37:18

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:18:00
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:51:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:37:09', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '56e7fd1e-b2e2-40a4-9a7c-0f69adf812ac'	System	12 Sep 2020 12:37:18
User entered '1'	System	12 Sep 2020 12:37:18

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:18:03
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:51:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:37:09', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '56e7fd1e-b2e2-40a4-9a7c-0f69adf812ac'	System	12 Sep 2020 12:37:18
User entered '1'	System	12 Sep 2020 12:37:18

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:37:15', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '56e7fd1e-b2e2-40a4-9a7c-0f69adf812ac'	System	12 Sep 2020 12:37:18
User entered '12 Sep 2020 08:37'	System	12 Sep 2020 12:37:18

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:59:31

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:59:31

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	11 Sep 2020 02:25:57
User entered 'Day 11'	System	11 Sep 2020 02:25:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:08:48', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'dc578786-f48f-4328-b590-86e33e1e4568'	System	13 Sep 2020 02:09:16
User entered 'Yes (Y)'	System	13 Sep 2020 02:09:16

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:08:57', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'dc578786-f48f-4328-b590-86e33e1e4568'	System	13 Sep 2020 02:09:16
User entered '98.4'	System	13 Sep 2020 02:09:16

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:09:01', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'dc578786-f48f-4328-b590-86e33e1e4568'	System	13 Sep 2020 02:09:16
User entered 'Yes (Y)'	System	13 Sep 2020 02:09:16

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:18:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:54:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:09:09', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'dc578786-f48f-4328-b590-86e33e1e4568'	System	13 Sep 2020 02:09:16
User entered '1'	System	13 Sep 2020 02:09:16

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:18:11
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:54:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:09:09', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'dc578786-f48f-4328-b590-86e33e1e4568'	System	13 Sep 2020 02:09:16
User entered '1'	System	13 Sep 2020 02:09:16

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:09:14', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'dc578786-f48f-4328-b590-86e33e1e4568'	System	13 Sep 2020 02:09:16
User entered '12 Sep 2020 22:09'	System	13 Sep 2020 02:09:16

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 02:25:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 02:25:57

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	12 Sep 2020 12:37:18
User entered 'Day 12'	System	12 Sep 2020 12:37:18

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:10', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '56e29507-01db-4f48-8c6b-ac61633d0a02'	System	14 Sep 2020 05:24:27
User entered 'Yes (Y)'	System	14 Sep 2020 05:24:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:17', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '56e29507-01db-4f48-8c6b-ac61633d0a02'	System	14 Sep 2020 05:24:27
User entered '98.2'	System	14 Sep 2020 05:24:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:21', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '56e29507-01db-4f48-8c6b-ac61633d0a02'	System	14 Sep 2020 05:24:27
User entered 'Yes (Y)'	System	14 Sep 2020 05:24:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:18:16
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:54:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:23', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '56e29507-01db-4f48-8c6b-ac61633d0a02'	System	14 Sep 2020 05:24:27
User entered '1'	System	14 Sep 2020 05:24:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:18:19
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:54:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:23', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '56e29507-01db-4f48-8c6b-ac61633d0a02'	System	14 Sep 2020 05:24:27
User entered '1'	System	14 Sep 2020 05:24:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:25', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '56e29507-01db-4f48-8c6b-ac61633d0a02'	System	14 Sep 2020 05:24:27
User entered '14 Sep 2020 01:24'	System	14 Sep 2020 05:24:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 12:37:18

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 12:37:18

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	13 Sep 2020 02:09:16
User entered 'Day 13'	System	13 Sep 2020 02:09:16

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:28:54', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f816b5c9-959d-46d7-a7f3-12bff9e87759'	System	15 Sep 2020 03:29:13
User entered 'Yes (Y)'	System	15 Sep 2020 03:29:13

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:02', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f816b5c9-959d-46d7-a7f3-12bff9e87759'	System	15 Sep 2020 03:29:13
User entered '98.5'	System	15 Sep 2020 03:29:13

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:06', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f816b5c9-959d-46d7-a7f3-12bff9e87759'	System	15 Sep 2020 03:29:13
User entered 'Yes (Y)'	System	15 Sep 2020 03:29:13

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:18:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:54:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:08', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f816b5c9-959d-46d7-a7f3-12bff9e87759'	System	15 Sep 2020 03:29:13
User entered '1'	System	15 Sep 2020 03:29:13

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:18:27
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:08', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f816b5c9-959d-46d7-a7f3-12bff9e87759'	System	15 Sep 2020 03:29:13
User entered '1'	System	15 Sep 2020 03:29:13

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:11', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f816b5c9-959d-46d7-a7f3-12bff9e87759'	System	15 Sep 2020 03:29:13
User entered '14 Sep 2020 23:29'	System	15 Sep 2020 03:29:13

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 02:09:16

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 02:09:16

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	14 Sep 2020 05:24:27
User entered 'Day 14'	System	14 Sep 2020 05:24:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:10', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'be14a5bc-b29b-4847-82e2-87e7a69ac946'	System	16 Sep 2020 00:57:29
User entered 'Yes (Y)'	System	16 Sep 2020 00:57:29

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:16', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'be14a5bc-b29b-4847-82e2-87e7a69ac946'	System	16 Sep 2020 00:57:29
User entered '97.9'	System	16 Sep 2020 00:57:29

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:19', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'be14a5bc-b29b-4847-82e2-87e7a69ac946'	System	16 Sep 2020 00:57:29
User entered 'Yes (Y)'	System	16 Sep 2020 00:57:29

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:33:44

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:18:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:54:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:21', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'be14a5bc-b29b-4847-82e2-87e7a69ac946'	System	16 Sep 2020 00:57:29
User entered '1'	System	16 Sep 2020 00:57:29

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:33:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CM updated' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 12:18:45
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 20:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:21', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'be14a5bc-b29b-4847-82e2-87e7a69ac946'	System	16 Sep 2020 00:57:29
User entered '1'	System	16 Sep 2020 00:57:29

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:23', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'be14a5bc-b29b-4847-82e2-87e7a69ac946'	System	16 Sep 2020 00:57:29
User entered '15 Sep 2020 20:57'	System	16 Sep 2020 00:57:29

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 05:24:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 05:24:27

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	15 Sep 2020 03:29:13
User entered 'Day 15'	System	15 Sep 2020 03:29:13

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:33:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T22:59:59', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '9e324830-0082-4f10-a5fc-ee735378a5b5'	System	17 Sep 2020 03:00:39
User entered 'Yes (Y)'	System	17 Sep 2020 03:00:39

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:33:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:00:15', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '9e324830-0082-4f10-a5fc-ee735378a5b5'	System	17 Sep 2020 03:00:39
User entered '98.2'	System	17 Sep 2020 03:00:39

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:00:29', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '9e324830-0082-4f10-a5fc-ee735378a5b5'	System	17 Sep 2020 03:00:39
User entered 'No (N)'	System	17 Sep 2020 03:00:39

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:00:35', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '9e324830-0082-4f10-a5fc-ee735378a5b5'	System	17 Sep 2020 03:00:39
User entered '16 Sep 2020 23:00'	System	17 Sep 2020 03:00:39

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 03:29:13

US3952033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 03:29:13

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:09:30', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'adbac6c1-3fda-479c-8070-fcf991da98d1'	System	02 Sep 2020 21:09:56
User entered 'None (1)'	System	02 Sep 2020 21:09:56

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:09:33', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'adbac6c1-3fda-479c-8070-fcf991da98d1'	System	02 Sep 2020 21:09:56
User entered 'No (N)'	System	02 Sep 2020 21:09:56

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:09:37', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'adbac6c1-3fda-479c-8070-fcf991da98d1'	System	02 Sep 2020 21:09:56
User entered 'No (N)'	System	02 Sep 2020 21:09:56

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:09:45', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'adbac6c1-3fda-479c-8070-fcf991da98d1'	System	02 Sep 2020 21:09:56
User entered 'None (1)'	System	02 Sep 2020 21:09:56

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:09:50', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'adbac6c1-3fda-479c-8070-fcf991da98d1'	System	02 Sep 2020 21:09:56
User entered '02 Sep 2020 17:09'	System	02 Sep 2020 21:09:56

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '02 Sep 2020 16:29'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '02 Sep 2020 18:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:05:36', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'a0224940-3305-4cfd-a2ec-be705e76036f'	System	03 Sep 2020 00:17:37
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 00:17:37

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:05:45', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'a0224940-3305-4cfd-a2ec-be705e76036f'	System	03 Sep 2020 00:17:37
User entered 'Yes (Y)'	System	03 Sep 2020 00:17:37

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

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

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:16:25', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'a0224940-3305-4cfd-a2ec-be705e76036f' User entered '4'	System	03 Sep 2020 00:17:37
	System	03 Sep 2020 00:17:37

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:16:30', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'a0224940-3305-4cfd-a2ec-be705e76036f'	System	03 Sep 2020 00:17:37
User entered 'No (N)'	System	03 Sep 2020 00:17:37

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:17:15', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'a0224940-3305-4cfd-a2ec-be705e76036f'	System	03 Sep 2020 00:17:37
User entered 'None (1)'	System	03 Sep 2020 00:17:37

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:17:31', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'a0224940-3305-4cfd-a2ec-be705e76036f'	System	03 Sep 2020 00:17:37
User entered '02 Sep 2020 20:17'	System	03 Sep 2020 00:17:37

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '02 Sep 2020 19:54'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 2'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:36:59', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '05404f65-f2d7-44a3-b258-01f6648b4231'	System	03 Sep 2020 21:42:27
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 21:42:27

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:33:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:37:09', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '05404f65-f2d7-44a3-b258-01f6648b4231'	System	03 Sep 2020 21:42:27
User entered 'Yes (Y)'	System	03 Sep 2020 21:42:27

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:33:44

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

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:38:34', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '05404f65-f2d7-44a3-b258-01f6648b4231'	System	03 Sep 2020 21:42:27
User entered '4'	System	03 Sep 2020 21:42:27

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:38:41', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '05404f65-f2d7-44a3-b258-01f6648b4231'	System	03 Sep 2020 21:42:27
User entered 'Yes (Y)'	System	03 Sep 2020 21:42:27

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:33:44

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:40:56', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '05404f65-f2d7-44a3-b258-01f6648b4231'	System	03 Sep 2020 21:42:27
User entered '50'	System	03 Sep 2020 21:42:27

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:42:04', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '05404f65-f2d7-44a3-b258-01f6648b4231'	System	03 Sep 2020 21:42:27
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 21:42:27

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:42:25', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '05404f65-f2d7-44a3-b258-01f6648b4231'	System	03 Sep 2020 21:42:27
User entered '03 Sep 2020 17:42'	System	03 Sep 2020 21:42:27

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 3'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:27:26', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '52e1a2f6-2c2b-4e88-9bd7-250886a8a1bb'	System	05 Sep 2020 01:28:51
User entered 'None (1)'	System	05 Sep 2020 01:28:51

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:33:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:27:29', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '52e1a2f6-2c2b-4e88-9bd7-250886a8a1bb'	System	05 Sep 2020 01:28:51
User entered 'No (N)'	System	05 Sep 2020 01:28:51

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:27:32', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '52e1a2f6-2c2b-4e88-9bd7-250886a8a1bb'	System	05 Sep 2020 01:28:51
User entered 'No (N)'	System	05 Sep 2020 01:28:51

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:28:37', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '52e1a2f6-2c2b-4e88-9bd7-250886a8a1bb'	System	05 Sep 2020 01:28:51
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 01:28:51

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:28:48', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '52e1a2f6-2c2b-4e88-9bd7-250886a8a1bb'	System	05 Sep 2020 01:28:51
User entered '04 Sep 2020 21:28'	System	05 Sep 2020 01:28:51

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 4'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:44:23', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0760546e-fe08-47a5-b007-113abe080349'	System	06 Sep 2020 01:44:40
User entered 'None (1)'	System	06 Sep 2020 01:44:40

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:33:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:44:26', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0760546e-fe08-47a5-b007-113abe080349'	System	06 Sep 2020 01:44:40
User entered 'No (N)'	System	06 Sep 2020 01:44:40

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:44:29', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0760546e-fe08-47a5-b007-113abe080349'	System	06 Sep 2020 01:44:40
User entered 'No (N)'	System	06 Sep 2020 01:44:40

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:44:32', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0760546e-fe08-47a5-b007-113abe080349'	System	06 Sep 2020 01:44:40
User entered 'None (1)'	System	06 Sep 2020 01:44:40

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:44:37', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0760546e-fe08-47a5-b007-113abe080349'	System	06 Sep 2020 01:44:40
User entered '05 Sep 2020 21:44'	System	06 Sep 2020 01:44:40

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 5'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:06:27', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3ea77858-3d82-41cc-aa55-fab99327252c'	System	07 Sep 2020 00:06:47
User entered 'None (1)'	System	07 Sep 2020 00:06:47

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:33:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:03:48', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3ea77858-3d82-41cc-aa55-fab99327252c'	System	07 Sep 2020 00:06:47
User entered 'No (N)'	System	07 Sep 2020 00:06:47

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:04:00', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3ea77858-3d82-41cc-aa55-fab99327252c'	System	07 Sep 2020 00:06:47
User entered 'No (N)'	System	07 Sep 2020 00:06:47

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:05:04', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3ea77858-3d82-41cc-aa55-fab99327252c'	System	07 Sep 2020 00:06:47
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 00:06:47

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:06:43', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3ea77858-3d82-41cc-aa55-fab99327252c'	System	07 Sep 2020 00:06:47
User entered '06 Sep 2020 20:06'	System	07 Sep 2020 00:06:47

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 6'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:21:32', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3ebe21f3-7360-4e24-b9a4-0be5704894ef'	System	07 Sep 2020 23:21:54
User entered 'None (1)'	System	07 Sep 2020 23:21:54

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:33:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:21:35', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3ebe21f3-7360-4e24-b9a4-0be5704894ef'	System	07 Sep 2020 23:21:54
User entered 'No (N)'	System	07 Sep 2020 23:21:54

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:21:39', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3ebe21f3-7360-4e24-b9a4-0be5704894ef'	System	07 Sep 2020 23:21:54
User entered 'No (N)'	System	07 Sep 2020 23:21:54

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:21:45', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3ebe21f3-7360-4e24-b9a4-0be5704894ef'	System	07 Sep 2020 23:21:54
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 23:21:54

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:21:50', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3ebe21f3-7360-4e24-b9a4-0be5704894ef'	System	07 Sep 2020 23:21:54
User entered '07 Sep 2020 19:21'	System	07 Sep 2020 23:21:54

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 7'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:37:39', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'e4ca9d17-1bb6-43ad-87bb-c6bee478c90e'	System	09 Sep 2020 00:38:17
User entered 'None (1)'	System	09 Sep 2020 00:38:17

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:33:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:37:42', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'e4ca9d17-1bb6-43ad-87bb-c6bee478c90e'	System	09 Sep 2020 00:38:17
User entered 'No (N)'	System	09 Sep 2020 00:38:17

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:37:47', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'e4ca9d17-1bb6-43ad-87bb-c6bee478c90e'	System	09 Sep 2020 00:38:17
User entered 'No (N)'	System	09 Sep 2020 00:38:17

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:37:55', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'e4ca9d17-1bb6-43ad-87bb-c6bee478c90e'	System	09 Sep 2020 00:38:17
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 00:38:17

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:38:11', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'e4ca9d17-1bb6-43ad-87bb-c6bee478c90e'	System	09 Sep 2020 00:38:17
User entered '08 Sep 2020 20:38'	System	09 Sep 2020 00:38:17

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:09:57', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3122b9cf-6888-4b3b-9888-74fa1a332067'	System	02 Sep 2020 21:10:23
User entered 'None (0)'	System	02 Sep 2020 21:10:23

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:10:03', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3122b9cf-6888-4b3b-9888-74fa1a332067'	System	02 Sep 2020 21:10:23
User entered 'None (0)'	System	02 Sep 2020 21:10:23

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:10:06', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3122b9cf-6888-4b3b-9888-74fa1a332067'	System	02 Sep 2020 21:10:23
User entered 'None (0)'	System	02 Sep 2020 21:10:23

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:10:08', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3122b9cf-6888-4b3b-9888-74fa1a332067'	System	02 Sep 2020 21:10:23
User entered 'None (0)'	System	02 Sep 2020 21:10:23

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:10:10', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3122b9cf-6888-4b3b-9888-74fa1a332067'	System	02 Sep 2020 21:10:23
User entered 'None (0)'	System	02 Sep 2020 21:10:23

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:10:13', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3122b9cf-6888-4b3b-9888-74fa1a332067'	System	02 Sep 2020 21:10:23
User entered 'None (0)'	System	02 Sep 2020 21:10:23

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:10:16', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3122b9cf-6888-4b3b-9888-74fa1a332067'	System	02 Sep 2020 21:10:23
User entered 'No (N)'	System	02 Sep 2020 21:10:23

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T17:10:21', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3122b9cf-6888-4b3b-9888-74fa1a332067'	System	02 Sep 2020 21:10:23
User entered '02 Sep 2020 17:10'	System	02 Sep 2020 21:10:23

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '02 Sep 2020 16:29'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '02 Sep 2020 18:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:17:39', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '9b71e23e-ef86-488d-bb24-de1fc7fe4244'	System	03 Sep 2020 00:18:22
User entered 'None (0)'	System	03 Sep 2020 00:18:22

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:17:47', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '9b71e23e-ef86-488d-bb24-de1fc7fe4244'	System	03 Sep 2020 00:18:22
User entered 'None (0)'	System	03 Sep 2020 00:18:22

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:17:50', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '9b71e23e-ef86-488d-bb24-de1fc7fe4244'	System	03 Sep 2020 00:18:22
User entered 'None (0)'	System	03 Sep 2020 00:18:22

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:17:53', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '9b71e23e-ef86-488d-bb24-de1fc7fe4244'	System	03 Sep 2020 00:18:22
User entered 'None (0)'	System	03 Sep 2020 00:18:22

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:18:03', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '9b71e23e-ef86-488d-bb24-de1fc7fe4244'	System	03 Sep 2020 00:18:22
User entered 'None (0)'	System	03 Sep 2020 00:18:22

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:18:06', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '9b71e23e-ef86-488d-bb24-de1fc7fe4244'	System	03 Sep 2020 00:18:22
User entered 'None (0)'	System	03 Sep 2020 00:18:22

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:18:14', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '9b71e23e-ef86-488d-bb24-de1fc7fe4244'	System	03 Sep 2020 00:18:22
User entered 'No (N)'	System	03 Sep 2020 00:18:22

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-02T20:18:20', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '9b71e23e-ef86-488d-bb24-de1fc7fe4244'	System	03 Sep 2020 00:18:22
User entered '02 Sep 2020 20:18'	System	03 Sep 2020 00:18:22

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '02 Sep 2020 19:54'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 2'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:42:34', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'efae9f4b-0b99-45e4-ba50-1c6d70cdbc95'	System	03 Sep 2020 21:43:29
User entered 'No interference with activity (1)'	System	03 Sep 2020 21:43:29

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:42:41', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'efae9f4b-0b99-45e4-ba50-1c6d70cdbc95'	System	03 Sep 2020 21:43:29
User entered 'Some interference with activity (2)'	System	03 Sep 2020 21:43:29

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:42:48', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'efae9f4b-0b99-45e4-ba50-1c6d70cdbd95'	System	03 Sep 2020 21:43:29
User entered 'Some interference with activity (2)'	System	03 Sep 2020 21:43:29

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:43:00', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'efae9f4b-0b99-45e4-ba50-1c6d70cdbd95'	System	03 Sep 2020 21:43:29
User entered 'Some interference with activity (2)'	System	03 Sep 2020 21:43:29

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:43:10', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'efae9f4b-0b99-45e4-ba50-1c6d70cdbc95'	System	03 Sep 2020 21:43:29
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	03 Sep 2020 21:43:29

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:43:15', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'efae9f4b-0b99-45e4-ba50-1c6d70cdbc95'	System	03 Sep 2020 21:43:29
User entered 'No interference with activity (1)'	System	03 Sep 2020 21:43:29

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:43:20', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'efae9f4b-0b99-45e4-ba50-1c6d70cdbc95'	System	03 Sep 2020 21:43:29
User entered 'No (N)'	System	03 Sep 2020 21:43:29

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-03T17:43:27', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'efae9f4b-0b99-45e4-ba50-1c6d70cdbc95'	System	03 Sep 2020 21:43:29
User entered '03 Sep 2020 17:43'	System	03 Sep 2020 21:43:29

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 3'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:28:57', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd1830728-6a39-4ae9-a642-202d76768567'	System	05 Sep 2020 01:30:10
User entered 'None (0)'	System	05 Sep 2020 01:30:10

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:29:11', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd1830728-6a39-4ae9-a642-202d76768567'	System	05 Sep 2020 01:30:10
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:30:10

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:29:19', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd1830728-6a39-4ae9-a642-202d76768567'	System	05 Sep 2020 01:30:10
User entered 'Some interference with activity (2)'	System	05 Sep 2020 01:30:10

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:29:39', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd1830728-6a39-4ae9-a642-202d76768567'	System	05 Sep 2020 01:30:10
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:30:10

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:29:48', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd1830728-6a39-4ae9-a642-202d76768567'	System	05 Sep 2020 01:30:10
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	05 Sep 2020 01:30:10

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:29:51', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd1830728-6a39-4ae9-a642-202d76768567'	System	05 Sep 2020 01:30:10
User entered 'None (0)'	System	05 Sep 2020 01:30:10

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:29:55', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd1830728-6a39-4ae9-a642-202d76768567'	System	05 Sep 2020 01:30:10
User entered 'No (N)'	System	05 Sep 2020 01:30:10

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-04T21:30:07', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd1830728-6a39-4ae9-a642-202d76768567'	System	05 Sep 2020 01:30:10
User entered '04 Sep 2020 21:30'	System	05 Sep 2020 01:30:10

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 4'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:44:43', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bfe5503f-340e-4a2b-b061-8100d3ac1dbc'	System	06 Sep 2020 01:45:21
User entered 'None (0)'	System	06 Sep 2020 01:45:21

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:44:49', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bfe5503f-340e-4a2b-b061-8100d3ac1dbc'	System	06 Sep 2020 01:45:21
User entered 'None (0)'	System	06 Sep 2020 01:45:21

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:45:00', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bfe5503f-340e-4a2b-b061-8100d3ac1dbc'	System	06 Sep 2020 01:45:21
User entered 'Some interference with activity (2)'	System	06 Sep 2020 01:45:21

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:45:03', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bfe5503f-340e-4a2b-b061-8100d3ac1dbc'	System	06 Sep 2020 01:45:21
User entered 'Some interference with activity (2)'	System	06 Sep 2020 01:45:21

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:45:06', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bfe5503f-340e-4a2b-b061-8100d3ac1dbc'	System	06 Sep 2020 01:45:21
User entered 'None (0)'	System	06 Sep 2020 01:45:21

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:45:09', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bfe5503f-340e-4a2b-b061-8100d3ac1dbc'	System	06 Sep 2020 01:45:21
User entered 'None (0)'	System	06 Sep 2020 01:45:21

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:45:12', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bfe5503f-340e-4a2b-b061-8100d3ac1dbc'	System	06 Sep 2020 01:45:21
User entered 'No (N)'	System	06 Sep 2020 01:45:21

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-05T21:45:17', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bfe5503f-340e-4a2b-b061-8100d3ac1dbc'	System	06 Sep 2020 01:45:21
User entered '05 Sep 2020 21:45'	System	06 Sep 2020 01:45:21

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 5'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:01:59', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f6c0fdb0-28e8-444d-ab1e-fa808a8c6495'	System	07 Sep 2020 00:03:12
User entered 'None (0)'	System	07 Sep 2020 00:03:12

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:02:06', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f6c0fdb0-28e8-444d-ab1e-fa808a8c6495'	System	07 Sep 2020 00:03:12
User entered 'Some interference with activity (2)'	System	07 Sep 2020 00:03:12

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:02:12', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f6c0fdb0-28e8-444d-ab1e-fa808a8c6495'	System	07 Sep 2020 00:03:12
User entered 'Some interference with activity (2)'	System	07 Sep 2020 00:03:12

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:02:19', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f6c0fdb0-28e8-444d-ab1e-fa808a8c6495'	System	07 Sep 2020 00:03:12
User entered 'Significant; prevents daily activity (3)'	System	07 Sep 2020 00:03:12

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:02:59', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f6c0fdb0-28e8-444d-ab1e-fa808a8c6495'	System	07 Sep 2020 00:03:12
User entered 'None (0)'	System	07 Sep 2020 00:03:12

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:02:36', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f6c0fdb0-28e8-444d-ab1e-fa808a8c6495'	System	07 Sep 2020 00:03:12
User entered 'None (0)'	System	07 Sep 2020 00:03:12

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:02:44', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f6c0fdb0-28e8-444d-ab1e-fa808a8c6495'	System	07 Sep 2020 00:03:12
User entered 'No (N)'	System	07 Sep 2020 00:03:12

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-06T20:03:07', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f6c0fdb0-28e8-444d-ab1e-fa808a8c6495'	System	07 Sep 2020 00:03:12
User entered '06 Sep 2020 20:03'	System	07 Sep 2020 00:03:12

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 6'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:22:01', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3dcd19e5-e966-4b99-8398-88dcc48cc5df'	System	07 Sep 2020 23:22:36
User entered 'None (0)'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:22:06', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3dcd19e5-e966-4b99-8398-88dcc48cc5df'	System	07 Sep 2020 23:22:36
User entered 'No interference with activity (1)'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:22:11', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3dcd19e5-e966-4b99-8398-88dcc48cc5df'	System	07 Sep 2020 23:22:36
User entered 'Some interference with activity (2)'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:22:14', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3dcd19e5-e966-4b99-8398-88dcc48cc5df'	System	07 Sep 2020 23:22:36
User entered 'Some interference with activity (2)'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:22:20', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3dcd19e5-e966-4b99-8398-88dcc48cc5df'	System	07 Sep 2020 23:22:36
User entered 'None (0)'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:22:22', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3dcd19e5-e966-4b99-8398-88dcc48cc5df'	System	07 Sep 2020 23:22:36
User entered 'None (0)'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:22:29', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3dcd19e5-e966-4b99-8398-88dcc48cc5df'	System	07 Sep 2020 23:22:36
User entered 'No (N)'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-07T19:22:34', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3dcd19e5-e966-4b99-8398-88dcc48cc5df'	System	07 Sep 2020 23:22:36
User entered '07 Sep 2020 19:22'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 7'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:38:20', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0a27c5c3-3f1e-469d-a93f-195f88e03b3f'	System	09 Sep 2020 00:39:16
User entered 'None (0)'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:38:26', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0a27c5c3-3f1e-469d-a93f-195f88e03b3f'	System	09 Sep 2020 00:39:16
User entered 'Some interference with activity (2)'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:38:32', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0a27c5c3-3f1e-469d-a93f-195f88e03b3f'	System	09 Sep 2020 00:39:16
User entered 'Some interference with activity (2)'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:38:38', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0a27c5c3-3f1e-469d-a93f-195f88e03b3f'	System	09 Sep 2020 00:39:16
User entered 'Some interference with activity (2)'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:38:41', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0a27c5c3-3f1e-469d-a93f-195f88e03b3f'	System	09 Sep 2020 00:39:16
User entered 'None (0)'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:38:43', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0a27c5c3-3f1e-469d-a93f-195f88e03b3f'	System	09 Sep 2020 00:39:16
User entered 'None (0)'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:38:51', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0a27c5c3-3f1e-469d-a93f-195f88e03b3f'	System	09 Sep 2020 00:39:16
User entered 'Yes (Y)'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-08T20:39:13', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0a27c5c3-3f1e-469d-a93f-195f88e03b3f'	System	09 Sep 2020 00:39:16
User entered '08 Sep 2020 20:39'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	07 Sep 2020 23:22:36
User entered 'Day 8'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T19:59:44', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '5ec6a6b1-c1fc-4641-90e0-9069867b5621'	System	09 Sep 2020 23:59:52
User entered 'No interference with activity (1)'	System	09 Sep 2020 23:59:52

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T19:59:48', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '5ec6a6b1-c1fc-4641-90e0-9069867b5621'	System	09 Sep 2020 23:59:52
User entered '09 Sep 2020 19:59'	System	09 Sep 2020 23:59:52

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	09 Sep 2020 00:39:16
User entered 'Day 9'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:26:10', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b5601cd7-5116-464a-b9c9-4d6d3c28bc5a'	System	11 Sep 2020 02:26:19
User entered 'Some interference with activity (2)'	System	11 Sep 2020 02:26:19

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:26:16', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'b5601cd7-5116-464a-b9c9-4d6d3c28bc5a'	System	11 Sep 2020 02:26:19
User entered '10 Sep 2020 22:26'	System	11 Sep 2020 02:26:19

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	09 Sep 2020 23:59:52
User entered 'Day 10'	System	09 Sep 2020 23:59:52

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:37:27', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'e8665c26-a85b-49d0-9692-b1d28982ead0'	System	12 Sep 2020 12:37:34
User entered 'No interference with activity (1)'	System	12 Sep 2020 12:37:34

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:37:31', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'e8665c26-a85b-49d0-9692-b1d28982ead0'	System	12 Sep 2020 12:37:34
User entered '12 Sep 2020 08:37'	System	12 Sep 2020 12:37:34

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:59:52

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:59:52

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	11 Sep 2020 02:26:19
User entered 'Day 11'	System	11 Sep 2020 02:26:19

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:09:22', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bbb18320-93d0-4965-a1e6-aed0845795c5'	System	13 Sep 2020 02:09:29
User entered 'Significant; prevents daily activity (3)'	System	13 Sep 2020 02:09:29

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:09:26', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bbb18320-93d0-4965-a1e6-aed0845795c5'	System	13 Sep 2020 02:09:29
User entered '12 Sep 2020 22:09'	System	13 Sep 2020 02:09:29

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 02:26:19

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 02:26:19

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	12 Sep 2020 12:37:34
User entered 'Day 12'	System	12 Sep 2020 12:37:34

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:30', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '4fb45db2-0662-48e7-9117-ee59217dc101'	System	14 Sep 2020 05:24:36
User entered 'Some interference with activity (2)'	System	14 Sep 2020 05:24:36

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:33', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '4fb45db2-0662-48e7-9117-ee59217dc101'	System	14 Sep 2020 05:24:36
User entered '14 Sep 2020 01:24'	System	14 Sep 2020 05:24:36

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 12:37:34

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 12:37:34

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	13 Sep 2020 02:09:29
User entered 'Day 13'	System	13 Sep 2020 02:09:29

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:23', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '014b683f-fdb1-450b-bbe0-c6c6ca7baf05'	System	15 Sep 2020 03:29:30
User entered 'No interference with activity (1)'	System	15 Sep 2020 03:29:30

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:26', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '014b683f-fdb1-450b-bbe0-c6c6ca7baf05'	System	15 Sep 2020 03:29:30
User entered '14 Sep 2020 23:29'	System	15 Sep 2020 03:29:30

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 02:09:29

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 02:09:29

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	14 Sep 2020 05:24:36
User entered 'Day 14'	System	14 Sep 2020 05:24:36

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:29', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bb3008c9-7334-43c2-8a27-c22834541c2c'	System	16 Sep 2020 00:57:35
User entered 'Some interference with activity (2)'	System	16 Sep 2020 00:57:35

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:31', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bb3008c9-7334-43c2-8a27-c22834541c2c'	System	16 Sep 2020 00:57:35
User entered '15 Sep 2020 20:57'	System	16 Sep 2020 00:57:35

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 05:24:36

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 05:24:36

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	15 Sep 2020 03:29:30
User entered 'Day 15'	System	15 Sep 2020 03:29:30

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:00:40', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'cb2e0576-f6c4-4d86-862a-07ffb94d73e4'	System	17 Sep 2020 03:00:48
User entered 'No interference with activity (1)'	System	17 Sep 2020 03:00:48

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:00:43', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'cb2e0576-f6c4-4d86-862a-07ffb94d73e4'	System	17 Sep 2020 03:00:48
User entered '16 Sep 2020 23:00'	System	17 Sep 2020 03:00:48

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 03:29:30

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 03:29:30

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	16 Sep 2020 00:57:35
User entered 'Day 16'	System	16 Sep 2020 00:57:35

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-17T22:21:32', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '37106b77-3c69-47c8-ac2d-87c0643288b0'	System	18 Sep 2020 02:21:41
User entered 'None (0)'	System	18 Sep 2020 02:21:41

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-17T22:21:38', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '37106b77-3c69-47c8-ac2d-87c0643288b0'	System	18 Sep 2020 02:21:41
User entered '17 Sep 2020 22:21'	System	18 Sep 2020 02:21:41

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 00:57:35

US3952033

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 00:57:35

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	07 Sep 2020 23:22:36
User entered 'Day 8'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T20:00:03', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '85eddf6a-5583-474c-b363-7a97b6033cc4'	System	10 Sep 2020 00:00:11
User entered 'No interference with activity (1)'	System	10 Sep 2020 00:00:11

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T20:00:06', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '85eddf6a-5583-474c-b363-7a97b6033cc4'	System	10 Sep 2020 00:00:11
User entered '09 Sep 2020 20:00'	System	10 Sep 2020 00:00:11

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	09 Sep 2020 00:39:16
User entered 'Day 9'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:26:21', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '16482d19-0573-44c3-a823-46cc54fb8663'	System	11 Sep 2020 02:26:28
User entered 'Some interference with activity (2)'	System	11 Sep 2020 02:26:28

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:26:24', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '16482d19-0573-44c3-a823-46cc54fb8663'	System	11 Sep 2020 02:26:28
User entered '10 Sep 2020 22:26'	System	11 Sep 2020 02:26:28

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	10 Sep 2020 00:00:11
User entered 'Day 10'	System	10 Sep 2020 00:00:11

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:37:36', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3dc875b6-9a52-472b-b30b-c2caa6bb97e0'	System	12 Sep 2020 12:37:40
User entered 'No interference with activity (1)'	System	12 Sep 2020 12:37:40

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:37:38', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3dc875b6-9a52-472b-b30b-c2caa6bb97e0'	System	12 Sep 2020 12:37:40
User entered '12 Sep 2020 08:37'	System	12 Sep 2020 12:37:40

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 00:00:11

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 00:00:11

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	11 Sep 2020 02:26:28
User entered 'Day 11'	System	11 Sep 2020 02:26:28

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:09:33', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'e73550ae-3039-4ceb-b2f0-b09567faeddb'	System	13 Sep 2020 02:09:37
User entered 'Significant; prevents daily activity (3)'	System	13 Sep 2020 02:09:37

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:09:36', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'e73550ae-3039-4ceb-b2f0-b09567faeddb'	System	13 Sep 2020 02:09:37
User entered '12 Sep 2020 22:09'	System	13 Sep 2020 02:09:37

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 02:26:28

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 02:26:28

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	12 Sep 2020 12:37:40
User entered 'Day 12'	System	12 Sep 2020 12:37:40

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:37', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '4ce235ce-12da-4509-a16c-ba118d537a0b'	System	14 Sep 2020 05:24:43
User entered 'Some interference with activity (2)'	System	14 Sep 2020 05:24:43

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:40', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '4ce235ce-12da-4509-a16c-ba118d537a0b'	System	14 Sep 2020 05:24:43
User entered '14 Sep 2020 01:24'	System	14 Sep 2020 05:24:43

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 12:37:40

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 12:37:40

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	13 Sep 2020 02:09:37
User entered 'Day 13'	System	13 Sep 2020 02:09:37

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:35', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '1ceac6c1-9d6c-4551-93a3-81f7fb41dcc8'	System	15 Sep 2020 03:29:41
User entered 'Some interference with activity (2)'	System	15 Sep 2020 03:29:41

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:38', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '1ceac6c1-9d6c-4551-93a3-81f7fb41dcc8'	System	15 Sep 2020 03:29:41
User entered '14 Sep 2020 23:29'	System	15 Sep 2020 03:29:41

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 02:09:37

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 02:09:37

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	14 Sep 2020 05:24:43
User entered 'Day 14'	System	14 Sep 2020 05:24:43

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:35', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd70d48e6-4f97-40b9-9128-962d253b2999'	System	16 Sep 2020 00:57:41
User entered 'Some interference with activity (2)'	System	16 Sep 2020 00:57:41

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:38', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd70d48e6-4f97-40b9-9128-962d253b2999'	System	16 Sep 2020 00:57:41
User entered '15 Sep 2020 20:57'	System	16 Sep 2020 00:57:41

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 05:24:43

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 05:24:43

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	15 Sep 2020 03:29:41
User entered 'Day 15'	System	15 Sep 2020 03:29:41

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:00:47', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'de393b25-740d-49c5-bd5a-0d6e8e2fc970'	System	17 Sep 2020 03:00:53
User entered 'No interference with activity (1)'	System	17 Sep 2020 03:00:53

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:00:50', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'de393b25-740d-49c5-bd5a-0d6e8e2fc970'	System	17 Sep 2020 03:00:53
User entered '16 Sep 2020 23:00'	System	17 Sep 2020 03:00:53

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 03:29:41

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 03:29:41

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	16 Sep 2020 00:57:41
User entered 'Day 16'	System	16 Sep 2020 00:57:41

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-17T22:21:47', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '48b1aecb-2e2d-41ec-aca3-701ff63565b1'	System	18 Sep 2020 02:21:53
User entered 'None (0)'	System	18 Sep 2020 02:21:53

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-17T22:21:50', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '48b1aecb-2e2d-41ec-aca3-701ff63565b1'	System	18 Sep 2020 02:21:53
User entered '17 Sep 2020 22:21'	System	18 Sep 2020 02:21:53

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 00:57:41

US3952033

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 00:57:41

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	07 Sep 2020 23:22:36
User entered 'Day 8'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T20:00:14', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '36fbe473-31c8-4cc5-a434-355bf48a8110'	System	10 Sep 2020 00:00:24
User entered 'No interference with activity (1)'	System	10 Sep 2020 00:00:24

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T20:00:22', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '36fbe473-31c8-4cc5-a434-355bf48a8110'	System	10 Sep 2020 00:00:24
User entered '09 Sep 2020 20:00'	System	10 Sep 2020 00:00:24

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 23:22:36

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	09 Sep 2020 00:39:16
User entered 'Day 9'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:26:29', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '2e349d41-7468-42bc-9879-1136e6f50624'	System	11 Sep 2020 02:26:35
User entered 'Some interference with activity (2)'	System	11 Sep 2020 02:26:35

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:26:33', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '2e349d41-7468-42bc-9879-1136e6f50624'	System	11 Sep 2020 02:26:35
User entered '10 Sep 2020 22:26'	System	11 Sep 2020 02:26:35

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 00:39:16

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	10 Sep 2020 00:00:24
User entered 'Day 10'	System	10 Sep 2020 00:00:24

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:37:42', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '251cc07b-83a0-4def-80fb-98a6b22a4db9'	System	12 Sep 2020 12:37:46
User entered 'Some interference with activity (2)'	System	12 Sep 2020 12:37:46

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:37:44', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '251cc07b-83a0-4def-80fb-98a6b22a4db9'	System	12 Sep 2020 12:37:46
User entered '12 Sep 2020 08:37'	System	12 Sep 2020 12:37:46

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 00:00:24

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 00:00:24

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	11 Sep 2020 02:26:35
User entered 'Day 11'	System	11 Sep 2020 02:26:35

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:09:40', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '7792dd1a-17a1-490a-9821-4bec6b7fceb'	System	13 Sep 2020 02:09:47
User entered 'Significant; prevents daily activity (3)'	System	13 Sep 2020 02:09:47

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:09:43', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '7792dd1a-17a1-490a-9821-4bec6b7fceb'	System	13 Sep 2020 02:09:47
User entered '12 Sep 2020 22:09'	System	13 Sep 2020 02:09:47

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 02:26:35

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 02:26:35

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	12 Sep 2020 12:37:46
User entered 'Day 12'	System	12 Sep 2020 12:37:46

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:45', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'e967bd1c-af8b-4d22-bb89-f8c2da624244'	System	14 Sep 2020 05:24:49
User entered 'Some interference with activity (2)'	System	14 Sep 2020 05:24:49

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:47', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'e967bd1c-af8b-4d22-bb89-f8c2da624244'	System	14 Sep 2020 05:24:49
User entered '14 Sep 2020 01:24'	System	14 Sep 2020 05:24:49

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 12:37:46

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 12:37:46

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	13 Sep 2020 02:09:47
User entered 'Day 13'	System	13 Sep 2020 02:09:47

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:42', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '97d759e4-29f1-4e8a-9546-f7b846832f54'	System	15 Sep 2020 03:29:47
User entered 'Some interference with activity (2)'	System	15 Sep 2020 03:29:47

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:44', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '97d759e4-29f1-4e8a-9546-f7b846832f54'	System	15 Sep 2020 03:29:47
User entered '14 Sep 2020 23:29'	System	15 Sep 2020 03:29:47

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 02:09:47

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 02:09:47

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	14 Sep 2020 05:24:49
User entered 'Day 14'	System	14 Sep 2020 05:24:49

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:43', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '911961bf-86a8-4b2c-9013-e3669b47a7f1'	System	16 Sep 2020 00:57:48
User entered 'Some interference with activity (2)'	System	16 Sep 2020 00:57:48

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:46', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '911961bf-86a8-4b2c-9013-e3669b47a7f1'	System	16 Sep 2020 00:57:48
User entered '15 Sep 2020 20:57'	System	16 Sep 2020 00:57:48

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 05:24:49

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 05:24:49

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	15 Sep 2020 03:29:47
User entered 'Day 15'	System	15 Sep 2020 03:29:47

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:01:18', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'debfb40e-b5e5-4de9-a805-b95561712eb9'	System	17 Sep 2020 03:01:24
User entered 'No interference with activity (1)'	System	17 Sep 2020 03:01:24

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:01:22', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'debf40e-b5e5-4de9-a805-b95561712eb9'	System	17 Sep 2020 03:01:24
User entered '16 Sep 2020 23:01'	System	17 Sep 2020 03:01:24

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 03:29:47

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 03:29:47

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	16 Sep 2020 00:57:48
User entered 'Day 16'	System	16 Sep 2020 00:57:48

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 10:33:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-17T22:21:55', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'dddf4452-1767-45a2-8c20-1a36b908a3ff'	System	18 Sep 2020 02:22:02
User entered 'None (0)'	System	18 Sep 2020 02:22:02

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-17T22:21:57', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'ddd4452-1767-45a2-8c20-1a36b908a3ff'	System	18 Sep 2020 02:22:02
User entered '17 Sep 2020 22:21'	System	18 Sep 2020 02:22:02

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 00:57:48

US3952033

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 00:57:48

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	07 Sep 2020 23:21:27
User entered 'Day 8'	System	07 Sep 2020 23:21:27

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T20:00:37', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '6a8b7367-7555-4364-8643-094d8af32459'	System	10 Sep 2020 00:00:48
User entered 'No (N)'	System	10 Sep 2020 00:00:48

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T20:00:43', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '6a8b7367-7555-4364-8643-094d8af32459'	System	10 Sep 2020 00:00:48
User entered '09 Sep 2020 20:00'	System	10 Sep 2020 00:00:48

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 23:21:27

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 23:21:27

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	09 Sep 2020 00:37:36
User entered 'Day 9'	System	09 Sep 2020 00:37:36

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:26:43', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bad2435e-709c-43e0-aa65-2e38babcd32d'	System	11 Sep 2020 02:26:53
User entered 'No (N)'	System	11 Sep 2020 02:26:53

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:26:49', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'bad2435e-709c-43e0-aa65-2e38babcd32d'	System	11 Sep 2020 02:26:53
User entered '10 Sep 2020 22:26'	System	11 Sep 2020 02:26:53

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 00:37:36

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 00:37:36

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	09 Sep 2020 23:59:31
User entered 'Day 10'	System	09 Sep 2020 23:59:31

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:37:56', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3672033f-0bbb-4c52-9e33-2dbb8ade9d25'	System	12 Sep 2020 12:38:14
User entered 'No (N)'	System	12 Sep 2020 12:38:14

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:38:11', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3672033f-0bbb-4c52-9e33-2dbb8ade9d25'	System	12 Sep 2020 12:38:14
User entered '12 Sep 2020 08:38'	System	12 Sep 2020 12:38:14

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:59:31

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:59:31

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	11 Sep 2020 02:25:57
User entered 'Day 11'	System	11 Sep 2020 02:25:57

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:09:47', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd7bf497e-3b6c-4648-997b-10f9f8b09ea3'	System	13 Sep 2020 02:09:51
User entered 'No (N)'	System	13 Sep 2020 02:09:51

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:09:50', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd7bf497e-3b6c-4648-997b-10f9f8b09ea3'	System	13 Sep 2020 02:09:51
User entered '12 Sep 2020 22:09'	System	13 Sep 2020 02:09:51

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 02:25:57

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 02:25:57

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	12 Sep 2020 12:37:18
User entered 'Day 12'	System	12 Sep 2020 12:37:18

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:51', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '72a00dd8-0098-4c81-a7b9-9ecf6da0edca'	System	14 Sep 2020 05:24:55
User entered 'No (N)'	System	14 Sep 2020 05:24:55

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:53', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '72a00dd8-0098-4c81-a7b9-9ecf6da0edca'	System	14 Sep 2020 05:24:55
User entered '14 Sep 2020 01:24'	System	14 Sep 2020 05:24:55

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 12:37:18

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 12:37:18

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	13 Sep 2020 02:09:16
User entered 'Day 13'	System	13 Sep 2020 02:09:16

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:48', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '82e91e17-397f-4406-bced-87c30bab1a89'	System	15 Sep 2020 03:29:55
User entered 'No (N)'	System	15 Sep 2020 03:29:55

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:51', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '82e91e17-397f-4406-bced-87c30bab1a89'	System	15 Sep 2020 03:29:55
User entered '14 Sep 2020 23:29'	System	15 Sep 2020 03:29:55

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 02:09:16

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 02:09:16

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	14 Sep 2020 05:24:27
User entered 'Day 14'	System	14 Sep 2020 05:24:27

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:52', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '6115ff61-d74d-46cc-a02d-742c559b42a0'	System	16 Sep 2020 00:58:01
User entered 'No (N)'	System	16 Sep 2020 00:58:01

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:57:57', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '6115ff61-d74d-46cc-a02d-742c559b42a0'	System	16 Sep 2020 00:58:01
User entered '15 Sep 2020 20:57'	System	16 Sep 2020 00:58:01

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 05:24:27

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 05:24:27

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	15 Sep 2020 03:29:13
User entered 'Day 15'	System	15 Sep 2020 03:29:13

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:01:41', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'de8831e5-d95b-4de4-aaea-2090a8710ff6'	System	17 Sep 2020 03:01:47
User entered 'No (N)'	System	17 Sep 2020 03:01:47

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:01:45', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'de8831e5-d95b-4de4-aaea-2090a8710ff6'	System	17 Sep 2020 03:01:47
User entered '16 Sep 2020 23:01'	System	17 Sep 2020 03:01:47

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 03:29:13

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 03:29:13

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
Data entry locked.	System	16 Sep 2020 00:57:29
User entered 'Day 16'	System	16 Sep 2020 00:57:29

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-17T22:22:05', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'a3a0082e-4978-401d-b81a-5bc3080601f2'	System	18 Sep 2020 02:22:10
User entered 'No (N)'	System	18 Sep 2020 02:22:10

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-17T22:22:07', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'a3a0082e-4978-401d-b81a-5bc3080601f2'	System	18 Sep 2020 02:22:10
User entered '17 Sep 2020 22:22'	System	18 Sep 2020 02:22:10

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 00:57:29

US3952033

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:09:51
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 00:57:29

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
Data entry locked.	System	07 Sep 2020 23:21:54
User entered 'Day 8'	System	07 Sep 2020 23:21:54

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T20:01:14', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '86726848-8995-4909-bcc0-f933b04bacf7'	System	10 Sep 2020 00:01:23
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 00:01:23

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-09T20:01:20', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '86726848-8995-4909-bcc0-f933b04bacf7'	System	10 Sep 2020 00:01:23
User entered '09 Sep 2020 20:01'	System	10 Sep 2020 00:01:23

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 23:21:54

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 23:21:54

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
Data entry locked.	System	09 Sep 2020 00:38:17
User entered 'Day 9'	System	09 Sep 2020 00:38:17

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:27:15', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '62d6af58-c260-483b-ac80-fbc55d90afe9'	System	11 Sep 2020 02:27:29
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	11 Sep 2020 02:27:29

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-10T22:27:24', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '62d6af58-c260-483b-ac80-fbc55d90afe9'	System	11 Sep 2020 02:27:29
User entered '10 Sep 2020 22:27'	System	11 Sep 2020 02:27:29

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 00:38:17

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 00:38:17

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
Data entry locked.	System	10 Sep 2020 00:01:23
User entered 'Day 10'	System	10 Sep 2020 00:01:23

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:38:17', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '54684bbc-ba96-476a-9540-7992739b90c2'	System	12 Sep 2020 12:38:24
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 12:38:24

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T08:38:20', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '54684bbc-ba96-476a-9540-7992739b90c2'	System	12 Sep 2020 12:38:24
User entered '12 Sep 2020 08:38'	System	12 Sep 2020 12:38:24

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 00:01:23

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 00:01:23

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
Data entry locked.	System	11 Sep 2020 02:27:29
User entered 'Day 11'	System	11 Sep 2020 02:27:29

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:10:03', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3e9bac09-b11f-4282-a089-9ff95a351c6e'	System	13 Sep 2020 02:10:11
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 02:10:11

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-12T22:10:08', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '3e9bac09-b11f-4282-a089-9ff95a351c6e'	System	13 Sep 2020 02:10:11
User entered '12 Sep 2020 22:10'	System	13 Sep 2020 02:10:11

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 02:27:29

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 02:27:29

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
Data entry locked.	System	12 Sep 2020 12:38:24
User entered 'Day 12'	System	12 Sep 2020 12:38:24

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:57', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0ed84b51-1177-49ca-bb96-20f048fedeb'	System	14 Sep 2020 05:25:05
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 05:25:05

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T01:24:59', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '0ed84b51-1177-49ca-bb96-20f048fedeb'	System	14 Sep 2020 05:25:05
User entered '14 Sep 2020 01:24'	System	14 Sep 2020 05:25:05

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 12:38:24

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 12:38:24

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
Data entry locked.	System	13 Sep 2020 02:10:11
User entered 'Day 13'	System	13 Sep 2020 02:10:11

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:56', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'a5189ab1-bc0c-42c5-b3c3-e55133f4016e'	System	15 Sep 2020 03:30:03
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 03:30:03

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-14T23:29:58', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'a5189ab1-bc0c-42c5-b3c3-e55133f4016e'	System	15 Sep 2020 03:30:03
User entered '14 Sep 2020 23:29'	System	15 Sep 2020 03:30:03

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 02:10:11

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 02:10:11

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
Data entry locked.	System	14 Sep 2020 05:25:05
User entered 'Day 14'	System	14 Sep 2020 05:25:05

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:58:01', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd5751493-88d7-4001-88c7-3a5cbf116d9d'	System	16 Sep 2020 00:58:08
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 00:58:08

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-15T20:58:03', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd5751493-88d7-4001-88c7-3a5cbf116d9d'	System	16 Sep 2020 00:58:08
User entered '15 Sep 2020 20:58'	System	16 Sep 2020 00:58:08

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 05:25:05

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 05:25:05

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(15)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
Data entry locked.	System	15 Sep 2020 03:30:03
User entered 'Day 15'	System	15 Sep 2020 03:30:03

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(15)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:01:52', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f355d353-d07d-4c57-856a-972b6d2ad9dd'	System	17 Sep 2020 03:01:58
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 03:01:58

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-16T23:01:55', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'f355d353-d07d-4c57-856a-972b6d2ad9dd'	System	17 Sep 2020 03:01:58
User entered '16 Sep 2020 23:01'	System	17 Sep 2020 03:01:58

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 03:30:03

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(15)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 03:30:03

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(16)

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
Data entry locked.	System	16 Sep 2020 00:58:08
User entered 'Day 16'	System	16 Sep 2020 00:58:08

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(16)

Generated On: 10 Jun 2021 10:33:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-17T22:22:12', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '693c85b9-7e3f-4a1d-ab93-ba1afe98fd57'	System	18 Sep 2020 02:22:17
User entered 'None (1)'	System	18 Sep 2020 02:22:17

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f60d87b5833dbae)', Time: '2020-09-17T22:22:14', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '693c85b9-7e3f-4a1d-ab93-ba1afe98fd57'	System	18 Sep 2020 02:22:17
User entered '17 Sep 2020 22:22'	System	18 Sep 2020 02:22:17

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 00:58:08

US3952033

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(16)

Generated On: 10 Jun 2021 10:33:44

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:10:01
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 00:58:08

US3952033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:53:15
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Sep 2020 17:48:29

US3952033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
Protocol deviation 'Per protocol, subject should be called at least 7 days after. Subject was called in 5 days.' inactivated.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:03
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 21:04:27
Protocol deviation created: Per protocol, subject should be called at least 7 days after. Subject was called in 5 days. Class: Non-compliance with visit schedule Code: Deviation.	(b) (4), (b) (6)	30 Oct 2020 21:04:23
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 20:53:17
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:53:15
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 13:31:41
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Deviation to be filed' (Site from System).	Nick Bart (b) (4)	29 Sep 2020 17:48:57
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Sep 2020 17:48:29
User entered '08 Sep 2020'	Nick Bart (b) (4)	29 Sep 2020 17:48:29

US3952033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:53:15
User entered 'Contact Made (CONTACT MADE)'	Nick Bart (b) (4)	29 Sep 2020 17:48:29

US3952033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:53:15
User entered empty.	Nick Bart (b) (4)	29 Sep 2020 17:48:29

US3952033

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 22:34:40
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Sep 2020 17:48:03

US3952033

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	29 Sep 2020 17:48:03

US3952033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 22:34:55
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Sep 2020 17:49:11

US3952033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 22:34:55
User entered '16 Sep 2020'	Nick Bart (b) (4)	29 Sep 2020 17:49:11

US3952033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 22:34:55
User entered 'Contact Made (CONTACT MADE)'	Nick Bart (b) (4)	29 Sep 2020 17:49:11

US3952033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 22:34:55
User entered empty.	Nick Bart (b) (4)	29 Sep 2020 17:49:11

US3952033

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 22:35:02
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Sep 2020 17:49:03

US3952033

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	29 Sep 2020 17:49:03

US3952033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:23:35
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Sep 2020 17:49:33

US3952033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:23:35
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 13:26:55
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Deviation filed. Multiple attempts over multiple days were made to reach subject, none successful until this date. Patient will be reeducated at next clinic visit.' (Site from System).	Nick Bart (b) (4)	29 Sep 2020 17:50:22
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Sep 2020 17:49:33
User entered '28 Sep 2020'	Nick Bart (b) (4)	29 Sep 2020 17:49:33

US3952033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:23:35
User entered 'Contact Made (CONTACT MADE)'	Nick Bart (b) (4)	29 Sep 2020 17:49:33

US3952033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:23:35
User entered empty.	Nick Bart (b) (4)	29 Sep 2020 17:49:33

US3952033

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:11:12
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Sep 2020 17:49:15

US3952033

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	29 Sep 2020 17:49:15

US3952033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:29
User closed query 'Per CDM: As the visit 2 Day 29 was not performed, please complete the dosing discontinuation form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:02:01
Query 'Per CDM: As the visit 2 Day 29 was not performed, please complete the dosing discontinuation form. Thank you. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 21:51:59
User opened query 'Per CDM: As the visit 2 Day 29 was not performed, please complete the dosing discontinuation form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:58:57
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 19:11:13

US3952033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:29
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:11:13

US3952033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:29
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:11:13

US3952033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'VISIT2'	System	14 Oct 2020 19:11:13

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User accepted default value 'Pre-Dose (PREDOSE)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:33:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User accepted default value 'Post-Dose (POSTDOSE)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:33:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:40

US3952033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:33:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:44
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:45

US3952033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:33:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:44
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:45

US3952033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:49
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:29

US3952033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:49
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:29

US3952033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:49
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:29

US3952033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:29

US3952033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:49
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:29

US3952033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:49
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:29

US3952033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:29

US3952033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:49
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:29

US3952033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 19:19:49
User entered empty.	System	13 Jan 2021 15:29:29

US3952033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:33:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:29

US3952033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:54
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:51

US3952033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:54
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:51

US3952033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:54
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:51

US3952033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:51

US3952033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:33:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:59
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:59

US3952033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:33:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:59

US3952033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:33:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:59
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:59

US3952033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:33:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:59
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:59

US3952033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:33:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:59

US3952033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:33:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:59

US3952033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:33:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:59
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:59

US3952033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:33:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:19:59
User entered empty.	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 15:29:59

US3952033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:33:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	13 Jan 2021 15:29:59

US3952033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:20:06
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 11NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:56:38
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 11NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' answered with 'Visit 3 Day 57 is present in EDC' (Site from DM).	Nick Bart (b) (4)	02 Dec 2020 17:22:38
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 11NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:22:45
User entered 'Yes (Y)'	Stephanie Melton (b) (4) (b) (4)	03 Nov 2020 16:48:27

US3952033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '1'	System	03 Nov 2020 16:48:27

US3952033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:21:03
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:35:13

US3952033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:21:03
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:35:13

US3952033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:21:03
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:35:13

US3952033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:21:03
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:35:13

US3952033

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:27:59
User entered 'Yes (Y)'	Nick Bart (b) (4)	20 Nov 2020 20:35:18

US3952033

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	20 Nov 2020 20:35:18

US3952033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:19
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:35:25

US3952033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:19
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:35:25

US3952033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:19
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:35:25

US3952033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:19
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:35:25

US3952033

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:26
User entered 'Yes (Y)'	Nick Bart (b) (4)	20 Nov 2020 20:35:30

US3952033

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	20 Nov 2020 20:35:30

US3952033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:31:40
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:35:39

US3952033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:31:40
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:35:39

US3952033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:31:40
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:35:39

US3952033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:31:40
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:35:39

US3952033

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:31:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4)	20 Nov 2020 20:35:48
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:35:45

US3952033

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	20 Nov 2020 20:35:48
User entered empty.	System	20 Nov 2020 20:35:45

US3952033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:24
User entered 'Yes (Y)'	Nick Bart (b) (4)	20 Nov 2020 20:36:02

US3952033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:24
User entered '11 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:36:02

US3952033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[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 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:24
User entered 'Clinic (Clinic)'	Nick Bart (b) (4)	20 Nov 2020 20:36:02

US3952033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'VISIT3'	System	20 Nov 2020 20:36:02

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:32
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:32
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:32
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:32
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:32
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:32
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:32
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:32
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:32
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:37:32
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered empty.	System	20 Nov 2020 20:36:20

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15

US3952033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15

US3952033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:33:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:39:17
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:36:16

US3952033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:33:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:39:17
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:36:16

US3952033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:39:25
User entered 'Yes (Y)'	Nick Bart (b) (4)	20 Nov 2020 20:36:34

US3952033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:39:25
User entered '11 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:36:34

US3952033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:39:25
User entered '16:19'	Nick Bart (b) (4)	20 Nov 2020 20:36:34

US3952033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '11 Nov 2020 16:19'	System	20 Nov 2020 20:36:34

US3952033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:40:29
User entered 'Yes (Y)'	Nick Bart (b) (4)	20 Nov 2020 20:36:07

US3952033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '1'	System	20 Nov 2020 20:36:07

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 64'	System	02 Sep 2020 21:08:05

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[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)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you been exposed to someone with 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)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20
Data entry locked.	System	02 Sep 2020 21:08:05
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 21:08:05

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20
Data entry locked.	System	02 Sep 2020 21:08:05
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 71'	System	02 Sep 2020 21:08:05

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[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)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you been exposed to someone with 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)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20
Data entry locked.	System	02 Sep 2020 21:08:05
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 21:08:05

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20
Data entry locked.	System	02 Sep 2020 21:08:05
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20
Data entry locked.	System	02 Sep 2020 21:08:05
User entered 'Day 78'	System	02 Sep 2020 21:08:05

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[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)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you been exposed to someone with 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)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20
Data entry locked.	System	02 Sep 2020 21:08:05
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 21:08:05

US3952033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:49:20
Data entry locked.	System	02 Sep 2020 21:08:05
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 21:08:05

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you been exposed to someone with 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)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you been exposed to someone with 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)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you been exposed to someone with 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)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you been exposed to someone with 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)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[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)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2020-12-18T14:42:15', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd473039a-fe02-4c62-a825-a3efda7d6448'	System	18 Dec 2020 19:42:33
User entered 'No (N)'	System	18 Dec 2020 19:42:33

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you been exposed to someone with 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)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2020-12-18T14:42:21', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd473039a-fe02-4c62-a825-a3efda7d6448'	System	18 Dec 2020 19:42:33
User entered 'No (N)'	System	18 Dec 2020 19:42:33

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2020-12-18T14:42:31', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd473039a-fe02-4c62-a825-a3efda7d6448' User entered '18 Dec 2020 14:42:31'	System	18 Dec 2020 19:42:33
	System	18 Dec 2020 19:42:33

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[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)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2020-12-25T08:33:14', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '655810ed-e753-4fcb-b080-5d788feb41a4'	System	25 Dec 2020 13:33:29
User entered 'No (N)'	System	25 Dec 2020 13:33:29

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Have you been exposed to someone with 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)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2020-12-25T08:33:19', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '655810ed-e753-4fcb-b080-5d788feb41a4'	System	25 Dec 2020 13:33:29
User entered 'No (N)'	System	25 Dec 2020 13:33:29

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2020-12-25T08:33:27', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '655810ed-e753-4fcb-b080-5d788feb41a4'	System	25 Dec 2020 13:33:29
User entered '25 Dec 2020 08:33:27'	System	25 Dec 2020 13:33:29

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[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)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2021-01-01T00:01:47', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '34675629-8981-4d59-a4c0-ef625dcc6095'	System	01 Jan 2021 05:02:04
User entered 'No (N)'	System	01 Jan 2021 05:02:04

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you been exposed to someone with 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)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2021-01-01T00:01:55', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '34675629-8981-4d59-a4c0-ef625dcc6095'	System	01 Jan 2021 05:02:04
User entered 'No (N)'	System	01 Jan 2021 05:02:04

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2021-01-01T00:02:00', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: '34675629-8981-4d59-a4c0-ef625dcc6095'	System	01 Jan 2021 05:02:04
User entered '01 Jan 2021 00:02:00'	System	01 Jan 2021 05:02:04

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[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)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2021-01-08T10:22:09', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'aa60b2d2-5b2f-4fd1-b136-dc8c4aec5e97'	System	08 Jan 2021 15:22:31
User entered 'No (N)'	System	08 Jan 2021 15:22:31

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Have you been exposed to someone with 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)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2021-01-08T10:22:20', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'aa60b2d2-5b2f-4fd1-b136-dc8c4aec5e97'	System	08 Jan 2021 15:22:31
User entered 'No (N)'	System	08 Jan 2021 15:22:31

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2021-01-08T10:22:28', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'aa60b2d2-5b2f-4fd1-b136-dc8c4aec5e97'	System	08 Jan 2021 15:22:31
User entered '08 Jan 2021 10:22:28'	System	08 Jan 2021 15:22:31

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[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)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2021-01-17T13:38:03', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd33bd3b9-eed2-45b7-85e6-534cb282c6e3'	System	17 Jan 2021 18:38:13
User entered 'No (N)'	System	17 Jan 2021 18:38:13

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

Have you been exposed to someone with 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)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2021-01-17T13:38:07', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd33bd3b9-eed2-45b7-85e6-534cb282c6e3'	System	17 Jan 2021 18:38:13
User entered 'No (N)'	System	17 Jan 2021 18:38:13

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ce84ebadcda3a954)', Time: '2021-01-17T13:38:11', User OID: 'PatientReportedOutcome (US3952033)', ODM File OID: 'd33bd3b9-eed2-45b7-85e6-534cb282c6e3'	System	17 Jan 2021 18:38:13
User entered '17 Jan 2021 13:38:11'	System	17 Jan 2021 18:38:13

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:49:20

US3952033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:33:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:20
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:49:20

US3952033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:23:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 01:09:36

US3952033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:23:02
User entered '30 Nov 2020'	(b) (4), (b) (6)	02 Dec 2020 01:09:36

US3952033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:23:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Dec 2020 01:09:36

US3952033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:23:02
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 01:09:36

US3952033

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:23:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 01:09:42

US3952033

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	02 Dec 2020 01:09:42

US3952033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:39:10
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 14-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	16 Feb 2021 20:17:13
' (Site from DM).		
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 14JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 20:17:12
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 14JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' answered with 'visit added to eCRF.' (Site from DM).	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:22:28
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 14-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:22:25
' answered with 'visit added to eCRF.' (Site from DM).		

US3952033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 14-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 04:56:48
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 14JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 22:34:15
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	31 Dec 2020 20:29:02

US3952033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:39:10
User entered '31 Dec 2020'	Atanas Filev (b) (4) (b) (4)	31 Dec 2020 20:29:02

US3952033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:39:10
User entered 'Contact Made (CONTACT MADE)'	Atanas Filev (b) (4) (b) (4)	31 Dec 2020 20:29:02

US3952033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:33:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:39:10
User entered empty.	Atanas Filev (b) (4) (b) (4)	31 Dec 2020 20:29:02

US3952033

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:39:23
User entered 'No (N)' reason for change: New Information	Atanas Filev (b) (4) (b) (4)	20 Jan 2021 19:23:29
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	31 Dec 2020 20:29:25

US3952033

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:33:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	20 Jan 2021 19:23:29
User entered '1'	System	31 Dec 2020 20:29:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:33:44

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 19:42:04
User closed query 'Per source, Dr. Van Der Leden spoke to subject on 07Oct20.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 19:42:00
Query 'Per source, Dr. Van Der Leden spoke to subject on 07Oct20.' answered with 'data updated' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 17:16:39
User entered '07 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:16:35
User opened query 'Per source, Dr. Van Der Leden spoke to subject on 07Oct20.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:53:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:52:51
User closed query 'Please complete the COVID-19 Severity assessment form if applicable. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:03:00
Query 'Please complete the COVID-19 Severity assessment form if applicable. Thank you.' answered with 'N/A' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 19:56:32
User opened query 'Please complete the COVID-19 Severity assessment form if applicable. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:00:46
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:47:53
User entered '08 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:21:22

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:33:44

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per source, Dr. Van Der Leden spoke with the subject at 1740. Please reconcile and update if needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 19:42:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 19:42:06
Query 'Per source, Dr. Van Der Leden spoke with the subject at 1740. Please reconcile and update if needed.' answered with 'data updated' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 17:16:42
User entered '17:40' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:16:35
User opened query 'Per source, Dr. Van Der Leden spoke with the subject at 1740. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:52:40
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:29:02
Query 'Please provide source.' answered with 'n/a' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 19:56:36
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 14:46:34
User entered '11:00'	(b) (4), (b) (6)	14 Oct 2020 19:21:22

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:33:44

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '07 Oct 2020 17:40'	System	02 Dec 2020 17:16:35
User entered '08 Oct 2020 11:00'	System	14 Oct 2020 19:21:22

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:33:44

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:52:42
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:29:22
Query 'Please provide source.' answered with 'n/a' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 19:56:41
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 14:57:44
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 14:57:24
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:57:17
Query 'Per 08Oct20 Progress note, this is not correct.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 14:57:16
User opened query 'Per 08Oct20 Progress note, this is not correct.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 14:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 14:48:18
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:47:57
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	(b) (4), (b) (6)	14 Oct 2020 19:21:22

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:33:44

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:14
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:47:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:21:22

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
Query 'Per CDM: Query for O2 saturation: it appears subject as <= 93% saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' canceled (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:50:37
User opened query 'Per CDM: Query for O2 saturation: it appears subject as <= 93% saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:50:05
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

Date

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:33:46
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:32:23
User entered '03 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
Query 'Per CDM: it appears subject as <= 93% saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' canceled (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:50:29
User opened query 'Per CDM: it appears subject as <= 93% saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:50:23
User closed query 'Per CDM: it appears Contact Date and Symptom Day 1 date are the same: 08OCT2020. Please review and confirm 08OCT2020 is the initial date of symptoms or make ALL updates accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:46:35
Query 'Per CDM: it appears Contact Date and Symptom Day 1 date are the same: 08OCT2020. Please review and confirm 08OCT2020 is the initial date of symptoms or make ALL updates accordingly.' answered with 'Confirmed correct as entered' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 16:16:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: it appears Contact Date and Symptom Day 1 date are the same: 08OCT2020. Please review and confirm 08OCT2020 is the initial date of symptoms or make ALL updates accordingly.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 10:33:06
	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '08 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per CDM: it appears subject as ≤ 93% saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 11:18:40
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:33:54
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:33:51
Query 'Per CDM: it appears subject as ≤ 93% saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' answered with 'not done' (Site from DM).	Nick Bart (b) (4)	13 Nov 2020 22:32:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
User opened query 'Per CDM: it appears subject as ≤ 93% saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:52:05
Query 'Per CDM: it appears subject as ≤ 93% saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' canceled (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:49:38

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: it appears subject as $\leq 93\%$ saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:48:24
Query 'Per CDM: it appears subject as $\leq 93\%$ saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' canceled (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:48:14
User opened query 'Per CDM: it appears subject as $\leq 93\%$ saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:47:53
User closed query 'Per CDM: it appears subject as $\leq 93\%$ saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:47:53
Query 'Please provide source.' answered with 'sent' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 21:52:56
Query 'Per CDM: it appears subject as $\leq 93\%$ saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' answered with 'please clarify query' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 16:19:03
User opened query 'Per CDM: it appears subject as $\leq 93\%$ saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 17:42:19
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:31:05
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 15:29:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '92'	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Query 'Per CDM: O2 saturation: it appears subject as </= 93% saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' canceled (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:49:19
User opened query 'Per CDM: O2 saturation: it appears subject as </= 93% saturation recorded in Symptom Log Days 1- 4 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:49:15
User entered '%'	System	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:33:56
User entered '101.3' F reason for change: New Information	Nick Bart (b) (4)	13 Nov 2020 22:34:44
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:32:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '102.2' F	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:33:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:25:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:25:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:34:51
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:25:35
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:36:33
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:34:07
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:05
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
Query 'Please provide source.' answered with 'sent' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 21:52:59
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:24:45
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:24:27
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:36:33
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:10
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:25:46
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:36:33
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:34:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:34:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:25:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:36:33
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

Body Aches

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:47:31
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 16:08:40
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 16:01:07
User closed query 'Source does not explicitly state that body aches were mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 16:00:59
Query 'Source does not explicitly state that body aches were mild. Please reconcile.' answered with 'progress note dated 07Oct2020 mentions subject reported "joint aches" as well as headache and fever' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 16:51:38
User opened query 'Source does not explicitly state that body aches were mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:15:31
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:38
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:34:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:25:49
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:36:33
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 16:08:41
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 16:01:09
User closed query 'Source does not explicitly state that headaches were mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 16:01:00
Query 'Source does not explicitly state that headaches were mild. Please reconcile.' answered with 'progress note dated 07Oct2020 mentions subject reported headache' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 16:51:39
User opened query 'Source does not explicitly state that headaches were mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:15:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:40
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08

PRODUCTION RELEASE (v12.003
EAB) (1725)

1691 of 4253

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:36:33
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:24
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:37:27
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:26:16
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:36:33
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:23
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:32:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:36:33
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:25
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:32:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:36:33
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:27
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:32:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:37:27
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:29
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:32:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:37:27
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

Diarrhea

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:31
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:32:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:37:27
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:32:23
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:25:57
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:37:27
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:29:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 2 (Day 2)' reason for change:	(b) (4), (b) (6)	14 Oct 2020 19:48:10
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:47
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33
User entered '04 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:08
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 19:48:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 19:48:10
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 19:33:31
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 07 Oct 2020 symptom log on log line 2. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 06:07:38
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 07 Oct 2020 symptom log on log line 2. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with "'Not done" is already entered for COVID assessment 07oct 2020' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 12:04:38
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 07 Oct 2020 symptom log on log line 2. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:27:23
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:12
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:50
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:10
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	14 Oct 2020 19:48:10
User entered empty.	System	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

Temperature

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:39:42
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 07 Oct 2020 symptom log on log line 2. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 13:54:29
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 07 Oct 2020 symptom log on log line 2. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 15:44:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 15:44:35
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 15:44:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 15:44:35
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 07 Oct 2020 symptom log on log line 2. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 06:07:56
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:16
User entered '103.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:55
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:18
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

Cough

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:34:59
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:20
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per 09Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:35:08
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:35:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
Query 'Per 09Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'Please clarify what about response is unclear. Source is marked clearly with response' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:20:46
User opened query 'Per 09Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:29:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:29:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:22
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

Difficulty Breathing

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:35:14
User closed query 'Per 09Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:35:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
Query 'Per 09Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'Please clarify what about response is unclear. Source is marked clearly with response' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:21:06
User opened query 'Per 09Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:29:41
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:29:16
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:23
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:35:17
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:25
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 16:01:25
User closed query 'Source does not explicitly state that body aches were gone. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 16:01:19
Query 'Source does not explicitly state that body aches were gone. Please reconcile.' answered with 'data updated to reflect ongoing symptom' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 17:01:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:01:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:00:11
User opened query 'Source does not explicitly state that body aches were gone. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:17:23
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:39
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:26
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 02:35:25
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:35:21
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:27
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:52:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 16:01:23
User closed query 'Source does not explicitly state that aches were gone. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 16:01:21
Query 'Source does not explicitly state that aches were gone. Please reconcile.' answered with 'data updated to reflect ongoing symptom' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 17:01:31
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:01:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:00:11
User opened query 'Source does not explicitly state that aches were gone. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:17:37
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:37
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:28
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 02:35:35
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:35:30
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:52:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:30
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:32
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:32
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:34
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:35:45
User closed query 'Per 09Oct20 telemedicine contact note, response is marked as "N/A". Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:35:41
Query 'Per 09Oct20 telemedicine contact note, response is marked as "N/A". Please confirm and update if necessary.' answered with 'N/A is not an option' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:21:30
User opened query 'Per 09Oct20 telemedicine contact note, response is marked as "N/A". Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:28:36
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:27:24
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User closed query 'Per 09Oct20 telemedicine contact note, response is marked as "N/A". Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:35:52
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:35:48
Query 'Per 09Oct20 telemedicine contact note, response is marked as "N/A". Please confirm and update if necessary.' answered with 'N/A is not an option' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:21:34
User opened query 'Per 09Oct20 telemedicine contact note, response is marked as "N/A". Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:28:43
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:27:22
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:40
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:00
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
	(b) (4), (b) (6)	
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
	(b) (4), (b) (6)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
	(b) (4), (b) (6)	
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User closed query 'Per 09Oct20 telemedicine contact note, response is marked as "N/A". Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:36:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:04
	(b) (4), (b) (6)	
Query 'Per 09Oct20 telemedicine contact note, response is marked as "N/A". Please confirm and update if necessary.' answered with 'N/A is not an option' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:21:38
	(b) (4), (b) (6)	
User opened query 'Per 09Oct20 telemedicine contact note, response is marked as "N/A". Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:28:50
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:27:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:43
	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31
	(b) (4), (b) (6)	

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
	(b) (4), (b) (6)	
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
	(b) (4), (b) (6)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
	(b) (4), (b) (6)	
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:21
	(b) (4), (b) (6)	
User closed query 'Per 09Oct20 telemedicine contact note, response is marked as "N/A". Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:36:18
	(b) (4), (b) (6)	
Query 'Per 09Oct20 telemedicine contact note, response is marked as "N/A". Please confirm and update if necessary.' answered with 'N/A is not an option' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:21:42
	(b) (4), (b) (6)	
User opened query 'Per 09Oct20 telemedicine contact note, response is marked as "N/A". Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:28:58
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:27:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:45
	(b) (4), (b) (6)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31
	(b) (4), (b) (6)	

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:23
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:35:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:35:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:14:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:48:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:33:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:47
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:36:37
User entered '05 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '10 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:49
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:36:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '93'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

Temperature

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:51
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:36:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '103.7' F	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:53
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:36:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:55
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:36:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:57
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:36:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

Difficulty Breathing

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:36:59
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:36:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:47:03
User closed query 'Per 10Oct20 telemedicine visit contact source, difficulty breathing was not circled. Please confirm whether if this is correct and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:46:52
Query 'Per 10Oct20 telemedicine visit contact source, difficulty breathing was not circled. Please confirm whether if this is correct and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:22:22
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:22:17
User opened query 'Per 10Oct20 telemedicine visit contact source, difficulty breathing was not circled. Please confirm whether if this is correct and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:35:09
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 15:34:05
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:01
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:36:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:04
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:36:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:06
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:36:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:13
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:36:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:11
User closed query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:37:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
Query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'all points updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:23:06
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:22:56
User opened query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:30:57
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:30:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:37:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
Query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:23:10
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:22:56
User opened query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:31:02
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:30:35
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
Query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:23:13
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:22:56
User opened query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:31:08
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:30:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

Vomiting

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:37:25
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
Query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:23:17
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:22:56
User opened query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:31:13
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:30:38
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:37:30
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
Query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:23:21
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:22:56
User opened query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:31:20
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:30:40
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:37:35
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:36:37
Query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:23:25
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:22:56
User opened query 'Per 10Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:31:26
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:30:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:52:36

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:44
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:37:20
User entered '06 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '11 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:46
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:37:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '89'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

Temperature

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:48
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:37:20
User entered missing code ND - Not Done; reason for	Nick Bart (b) (4)	13 Nov 2020 22:37:20
change Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '101.9' F	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:51
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:37:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:25
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:37:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:27
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:37:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:29
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:37:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:31
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:37:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:54
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:37:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:03
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:37:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:01
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:37:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:37:58
User closed query 'Per 11Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:37:56
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
Query 'Per 11Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:24:17
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:24:12
User opened query 'Per 11Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:33:38
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:33:18
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per 11Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:38:07
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:05
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
Query 'Per 11Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:24:20
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:24:12
User opened query 'Per 11Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:33:49
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:33:23
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:09
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:37:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User closed query 'Per 10Oct20 telemedicine contact note, vomiting is not circled. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:38:13
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:11
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
Query 'Per 10Oct20 telemedicine contact note, vomiting is not circled. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:24:24
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:24:12
User opened query 'Per 10Oct20 telemedicine contact note, vomiting is not circled. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:32:38
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:32:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

Diarrhea

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per 11Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:38:17
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
Query 'Per 11Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:24:28
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:24:12
User opened query 'Per 11Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:34:08
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:34:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:21
User closed query 'Per 11Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:38:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:37:20
Query 'Per 11Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:24:32
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:24:12
User opened query 'Per 11Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:34:02
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:33:52
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:54:27

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:38
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered '07 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '12 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:15
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '95'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

Temperature

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:10:38
User closed query 'Per source, subject had fever on 7Oct20. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 17:10:35
Query 'Per source, subject had fever on 7Oct20. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 17:02:21
User entered '101.9' F reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:02:17
User opened query 'Per source, subject had fever on 7Oct20. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:50:45
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 02:50:16
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:17
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '102.7' F	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:19
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:57:45
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:21
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:24
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

Difficulty Breathing

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:27
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:48:31
User closed query 'Per Telemedicine contact note on 12Oct20, difficulty breathing is not circled. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:48:20
Query 'Per Telemedicine contact note on 12Oct20, difficulty breathing is not circled. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:25:44
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:25:37
User opened query 'Per Telemedicine contact note on 12Oct20, difficulty breathing is not circled. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 15:42:29
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

Fatigue

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:29
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:11
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:13
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:06
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:08
User closed query 'Per 12Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:38:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
Query 'Per 12Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:25:47
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:25:37
User opened query 'Per 12Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:35:07
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:34:51
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:02
User closed query 'Per 12Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:38:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
Query 'Per 12Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:25:51
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:25:37
User opened query 'Per 12Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:35:13
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:34:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:39:00
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:58
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:38:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:56
User closed query 'Per 12Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:38:50
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
Query 'Per 12Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:25:54
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:25:37
User opened query 'Per 12Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:35:53
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:35:46
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:38:52
User closed query 'Per 12Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:38:47
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:38:03
Query 'Per 12Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:25:58
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:25:37
User opened query 'Per 12Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:36:03
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:35:55
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 19:57:13

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:49:26
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:40:02
User entered '08 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:40:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '13 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:20:46
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:40:02
User entered missing code ND - Not Done; reason for	Nick Bart (b) (4)	13 Nov 2020 22:40:02
change Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '94'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

Temperature

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:19:50
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:40:02
User entered '102.2' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:40:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '102.1' F	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:20:56
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:40:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:40:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:38
User closed query 'Source does not explicitly state that cough was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:46:35
Query 'Source does not explicitly state that cough was mild. Please reconcile.' answered with 'Per site call, if severity unknown, Mild is to be selected.' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:14:15
User opened query 'Source does not explicitly state that cough was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:21:58
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:40:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:40:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:44
User closed query 'Source does not explicitly state that shortness of breath was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:46:41
Query 'Source does not explicitly state that shortness of breath was mild. Please reconcile.' answered with 'Per site call, if severity unknown, Mild is to be selected.' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:14:20
User opened query 'Source does not explicitly state that shortness of breath was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:22:20
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:22:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

Difficulty Breathing

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:49
User closed query 'Source does not explicitly state that difficulty breathing was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:46:47
Query 'Source does not explicitly state that difficulty breathing was mild. Please reconcile.' answered with 'Per site call, if severity unknown, Mild is to be selected.' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:14:23
User opened query 'Source does not explicitly state that difficulty breathing was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:22:48
User closed query 'Per 13Oct20 Telemedicine contact note, difficulty breathing not circled. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:50:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:40:02
Query 'Per 13Oct20 Telemedicine contact note, difficulty breathing not circled. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:27:52
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:27:34
User opened query 'Per 13Oct20 Telemedicine contact note, difficulty breathing not circled. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:45:47
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 15:45:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:48:24
User closed query 'Source does not explicitly state that fatigue was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:46:52
Query 'Source does not explicitly state that fatigue was mild. Please reconcile.' answered with 'Per site call, if severity unknown, Mild is to be selected.' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:14:27
User opened query 'Source does not explicitly state that fatigue was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:23:06
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:40:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:40:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Source does not explicitly state that myalgia was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:46:59
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:46:56
Query 'Source does not explicitly state that myalgia was mild. Please reconcile.' answered with 'Per site call, if severity unknown, Mild is to be selected.' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:14:31
User opened query 'Source does not explicitly state that myalgia was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:23:23
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:40:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:40:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

Body Aches

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Source does not explicitly state that body aches were mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:47:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:02
Query 'Source does not explicitly state that body aches were mild. Please reconcile.' answered with 'Per site call, if severity unknown, Mild is to be selected.' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:14:34
User opened query 'Source does not explicitly state that body aches were mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:23:44
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:40:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:40:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Source does not explicitly state that headache was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:47:14
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:11
Query 'Source does not explicitly state that headache was mild. Please reconcile.' answered with 'Per site call, if severity unknown, Mild is to be selected.' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:14:37
User opened query 'Source does not explicitly state that headache was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:23:59
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:23:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:43
User closed query 'Source does not explicitly state that lost of taste was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:47:18
Query 'Source does not explicitly state that lost of taste was mild. Please reconcile.' answered with 'Per site call, if severity unknown, Mild is to be selected.' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:14:41
User opened query 'Source does not explicitly state that lost of taste was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:24:16
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:24:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Source does not explicitly state that loss of smell was mild. Please reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:47:21
Query 'Source does not explicitly state that loss of smell was mild. Please reconcile.' answered with 'Per site call, if severity unknown, Mild is to be selected.' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:14:44
User opened query 'Source does not explicitly state that loss of smell was mild. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:24:39
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:23
User closed query 'Per 13Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:51:05
Query 'Per 13Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:27:58
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:27:34
User opened query 'Per 13Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:36:36
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:36:22
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:25:14
User closed query 'Per 13Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:51:03
Query 'Per 13Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:28:03
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:27:34
User opened query 'Per 13Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:36:38
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:35
User closed query 'Per Illness visit source on 08Oct20, subject did not have nausea. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:47:29
Query 'Per Illness visit source on 08Oct20, subject did not have nausea. Please reconcile.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:15:16
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	21 Dec 2020 20:15:12
User opened query 'Per Illness visit source on 08Oct20, subject did not have nausea. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:25:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:25:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

Vomiting

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:32
User closed query 'Per Illness visit source on 08Oct20, subject did not have vomiting. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:47:26
Query 'Per Illness visit source on 08Oct20, subject did not have vomiting. Please reconcile.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:15:19
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	21 Dec 2020 20:15:12
User opened query 'Per Illness visit source on 08Oct20, subject did not have vomiting. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:26:48
User closed query 'Per 13Oct20 Telemedicine contact note, vomiting not circled. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:51:13
Query 'Per 13Oct20 Telemedicine contact note, vomiting not circled. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:28:07
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:27:34
User opened query 'Per 13Oct20 Telemedicine contact note, vomiting not circled. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:46:54
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 15:46:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:26:53
User closed query 'Per 13Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:51:07
Query 'Per 13Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:28:12
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:27:34
User opened query 'Per 13Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:36:57
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:36:51
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:47:40
User closed query 'Per Illness visit source on 08Oct20, severity is not provided. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:47:37
Query 'Per Illness visit source on 08Oct20, severity is not provided. Please reconcile.' answered with 'Per site call, if severity unknown, Mild is to be selected.' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:15:07
User opened query 'Per Illness visit source on 08Oct20, severity is not provided. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:27:33
User closed query 'Per 13Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:51:10
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:40:02
Query 'Per 13Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:28:17
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:27:34
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:37:09
User opened query 'Per 13Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:37:07
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	14 Oct 2020 20:00:58

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 7 (Day 7)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:27:59
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:43:00
User entered '09 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:43:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '14 Oct 2020'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:28:00
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:43:00
User entered '92' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:43:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '95'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:28:03
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:43:00
User entered '103.1' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:43:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '98.4' F	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:28:07
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:43:00
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:43:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:38:19
Query 'Per 14Oct20 Telemedicine contact note, this is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:38:17
User opened query 'Per 14Oct20 Telemedicine contact note, this is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:48:33
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 15:47:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:28:08
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:43:00
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:43:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:28:13
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:43:00
User entered 'Severe (Severe)' reason for change:	Nick Bart (b) (4)	13 Nov 2020 22:43:00
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

Difficulty Breathing

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:28:14
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:43:00
User entered 'Severe (Severe)' reason for change:	Nick Bart (b) (4)	13 Nov 2020 22:43:00
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:38:28
Query 'Per 14Oct20 Telemedicine contact note, difficulty breathing not circled. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:38:26
User opened query 'Per 14Oct20 Telemedicine contact note, difficulty breathing not circled. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:51:49
Query 'Per 13Oct20 Telemedicine contact note, difficulty breathing not circled. Please confirm that this was asked and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:51:40
User opened query 'Per 13Oct20 Telemedicine contact note, difficulty breathing not circled. Please confirm that this was asked and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:49:29
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:55
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

Fatigue

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:28:17
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:43:00
User entered 'Severe (Severe)' reason for change:	Nick Bart (b) (4)	13 Nov 2020 22:43:00
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:28:31
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:51:23
Query 'Please provide source.' answered with 'sent' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 21:53:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 20:47:18
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:50:39
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 15:50:17
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:28:33
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:51:27
Query 'Please provide source.' answered with 'sent' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 21:53:21
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 20:47:18
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:50:53
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 15:50:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per Illness visit source on 09Oct20, neither loss of taste or smell is circled. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:55:59
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:55:55
Query 'Per Illness visit source on 09Oct20, neither loss of taste or smell is circled. Please reconcile. ' answered with 'When neither option is circled in source, it is because both symptoms were experienced. When only one symptom experienced, that is reflected by circling that specific symptom out of the two presented.' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 17:08:31
User opened query 'Per Illness visit source on 09Oct20, neither loss of taste or smell is circled. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:29:39
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:29:32
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per Illness visit source on 09Oct20, neither loss of taste or smell is circled. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:56:00
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:55:57
Query 'Per Illness visit source on 09Oct20, neither loss of taste or smell is circled. Please reconcile.' answered with 'When neither option is circled in source, it is because both symptoms were experienced. When only one symptom experienced, that is reflected by circling that specific symptom out of the two presented.' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 17:08:35
User opened query 'Per Illness visit source on 09Oct20, neither loss of taste or smell is circled. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:29:27
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:28:57
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:39:04
Query 'Per 14Oct20 Telemedicine contact note, response enter is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:38:38
User opened query 'Per 14Oct20 Telemedicine contact note, response enter is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:52:30
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 15:51:16
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
Query 'Per 14Oct20 Telemedicine contact note, response entered is unclear. Please confirm and update if necessary.' canceled (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:38:44
	(b) (4), (b) (6)	29 Oct 2020 18:38:42
User opened query 'Per 14Oct20 Telemedicine contact note, response entered is unclear. Please confirm and update if necessary.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:02:30
	(b) (4), (b) (6)	29 Oct 2020 15:51:19
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:38:50
Query 'Per 14Oct20 Telemedicine contact note, response entered is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:38:47
User opened query 'Per 14Oct20 Telemedicine contact note, response entered is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:19:29
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:18:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:30:03
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:43:00
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:43:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:30:04
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:43:00
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:43:00
Query 'Per 14Oct20 Telemedicine contact note, response entered is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:38:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:38:53
User opened query 'Per 14Oct20 Telemedicine contact note, response entered is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:18:47
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:17:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	14 Oct 2020 20:46:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 8 (Day 8)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:31:00
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:46:31
User entered '10 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:46:31
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:55:39
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:55:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '15 Oct 2020'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:31:05
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:46:31
User entered '93' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:46:31
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '97'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:31:08
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:46:31
User entered '103.7' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:46:31
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '99.6' F	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
	(b) (4), (b) (6)	
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
	(b) (4), (b) (6)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
	(b) (4), (b) (6)	
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User closed query 'Per Illness visit source on 10Oct20, writing is unclear. Please confirm if moderate or mild.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:55:23
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:53:53
	(b) (4), (b) (6)	
Query 'Per Illness visit source on 10Oct20, writing is unclear. Please confirm if moderate or mild.' answered with 'Confirmed as "moderate"' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 17:09:35
	(b) (4), (b) (6)	
User opened query 'Per Illness visit source on 10Oct20, writing is unclear. Please confirm if moderate or mild.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:32:39
	(b) (4), (b) (6)	
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:46:31
	(b) (4), (b) (6)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:46:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:39:43
	(b) (4), (b) (6)	
Query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:39:36
	(b) (4), (b) (6)	
User opened query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:44:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:20:20
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
	(b) (4), (b) (6)	

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Nick Bart (b) (4) [REDACTED]	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:39:45
Query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:39:42
User opened query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:44:50
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:20:22
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:32:54
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:51:33
Query 'Please provide source.' answered with 'sent' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 21:53:32
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 20:47:28
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:45:18
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:45:05
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:32:55
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:51:35
Query 'Please provide source.' answered with 'sent' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 21:53:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 20:47:28
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:45:29
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:45:07
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User closed query 'Per Illness visit source on 09Oct20, the severity is incorrect. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:55:13
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:55:12
Query 'Per Illness visit source on 09Oct20, the severity is incorrect. Please reconcile.' answered with 'data updated' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 17:09:58
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:09:52
User opened query 'Per Illness visit source on 09Oct20, the severity is incorrect. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:33:35
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:46:31
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:46:31
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:39:57
Query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:39:56
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:45:54
User opened query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:45:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:40:07
Query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:40:01
User opened query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:46:02
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:45:52
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:40:08
Query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:40:04
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:46:49
User opened query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:46:37
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:48:46
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:46:31
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:46:31
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

Vomiting

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:40:17
Query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:40:15
User opened query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:47:08
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:46:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

Diarrhea

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
Query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:40:30
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:40:25
User opened query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:47:33
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:47:18
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
Query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:40:31
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:40:28
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 16:47:47
User opened query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:47:45
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 12:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 9 (Day 9)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:34:01
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:47:58
User entered '11 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:47:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '16 Oct 2020'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:34:05
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:47:58
User entered '89' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:47:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '97'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:34:07
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:47:58
User entered '101.9' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:47:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '98.4' F	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:34:12
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:47:58
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:47:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:34:15
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:47:58
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:47:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:34:17
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:47:58
User entered 'Severe (Severe)' reason for change:	Nick Bart (b) (4)	13 Nov 2020 22:47:58
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:34:20
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:47:58
User entered 'Severe (Severe)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:47:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:40:52
Query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:40:50
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 17:03:58
User opened query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 17:03:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:34:21
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:47:58
User entered 'Severe (Severe)' reason for change:	Nick Bart (b) (4)	13 Nov 2020 22:47:58
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 17:04:13
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 17:04:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:34:27
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:47:58
User entered 'Severe (Severe)' reason for change:	Nick Bart (b) (4)	13 Nov 2020 22:47:58
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:34:32
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:47:58
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:47:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:41:04
Query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:40:59
User opened query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 17:05:01
Query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 17:04:45
User opened query 'Per 15Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 17:04:43
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 17:04:32
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:34:33
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:47:58
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:47:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:41:03
Query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:41:01
User opened query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 17:05:18
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 17:05:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:41:17
Query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:41:14
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 17:05:31
User opened query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 17:05:28
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:41:20
Query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:41:16
User opened query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 17:05:45
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 17:05:39
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:41:56
Query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:41:53
User opened query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 17:05:57
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 17:05:51
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:34:52
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:47:58
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:47:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:42:03
Query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:41:59
User opened query 'Per 16Oct20 telemedicine contact note, response is unclear. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 17:06:16
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 17:06:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	16 Oct 2020 21:01:25

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 10 (Day 10)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:35:03
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:49:42
User entered '12 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:49:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '17 Oct 2020'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:35:05
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:49:42
User entered '95' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:49:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '97'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:35:07
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:49:42
User entered '102.7' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:49:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '97.9' F	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:35:12
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:49:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:49:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:35:19
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:49:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:49:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:35:22
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:35:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:35:26
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:49:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:49:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:01
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:49:42
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:49:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:08
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:49:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:49:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:09
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:49:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:49:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:19
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:49:42
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:49:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:20
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:49:42
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:49:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:24
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:49:42
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:49:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:32
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:26
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:24:14

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 11 (Day 11)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:42
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:51:41
User entered '13 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:51:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '18 Oct 2020'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:45
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:51:41
User entered '94' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:51:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '99'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:47
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:51:41
User entered '102.1' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:51:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '98.2' F	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:50
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:51:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:51:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:53
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:51:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:51:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:36:57
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:51:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:51:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:37:05
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:37:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:37:15
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:51:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:51:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:37:19
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:51:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:51:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:37:21
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:51:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:51:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:37:33
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:51:41
User entered 'None (None)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:51:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	19 Oct 2020 13:26:08

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 12 (Day 12)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:37:40
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:53:28
User entered '14 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:53:28
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '19 Oct 2020'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:37:47
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:53:15
User entered '95' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:53:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '99'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:37:49
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:53:15
User entered '98.4' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:53:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '98.2' F	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:49:57
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 19:49:32
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:49:08
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:53:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:53:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Moderate (Moderate)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:38:24
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:53:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:53:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:38:27
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:53:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:53:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:38:29
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:53:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:53:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:05:29

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 13 (Day 13)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:38:49
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:54:48
User entered '15 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:54:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '20 Oct 2020'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:38:51
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:54:48
User entered '97' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:54:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '99'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

Temperature

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:38:55
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:54:48
User entered '99.6' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:54:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '97.8' F	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:39:05
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:54:48
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:54:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

Fatigue

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:39:12
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:54:48
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:54:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:39:26
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:54:48
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:54:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:39:27
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:54:48
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:54:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:39:49
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:54:48
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:54:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	20 Oct 2020 21:06:12

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 14 (Day 14)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:40:06
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:56:15
User entered '16 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:56:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '21 Oct 2020'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:40:09
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:56:15
User entered '97' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:56:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '99'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:40:14
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:56:15
User entered '98.4' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:56:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '98.2' F	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:40:16
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:56:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:56:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:40:22
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:56:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:56:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:40:26
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:56:15
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:56:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:40:31
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:56:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:56:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:40:50
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:56:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:56:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:40:41
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:56:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:56:15
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	22 Oct 2020 15:18:10

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 15 (Day 15)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:41:05
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:57:50
User entered '17 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:57:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '22 Oct 2020'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:41:12
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:57:50
User entered '97' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:57:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '99'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:41:13
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:57:50
User entered '97.9' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:57:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '98.5' F	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:41:18
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:57:50
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:57:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:41:24
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:57:50
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:57:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:41:38
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:57:50
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:57:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	23 Oct 2020 17:56:15

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 16 (Day 16)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:41:46
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:59:00
User entered '18 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:59:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '23 Oct 2020'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '99'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:41:50
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:59:00
User entered '98.2' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:59:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '97.8' F	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:42:00
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:59:00
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:59:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

Fatigue

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:42:05
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:59:00
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:59:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:42:40
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:59:00
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:59:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:31:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 17 (Day 17)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:42:53
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:59:51
User entered '19 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:59:51
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '24 Oct 2020'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '99'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:43:13
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:59:51
User entered '98.2' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:59:51
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '97.9' F	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:43:21
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:59:51
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:59:51
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:44:01
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:59:51
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:59:51
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:44:14
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 22:59:51
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 22:59:51
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:39:44

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 18 (Day 18)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:44:22
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 23:00:43
User entered '20 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 23:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '25 Oct 2020'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '0'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '99'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:44:29
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 23:00:43
User entered '97.8' F reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 23:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered '97.9' F	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:44:32
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 23:00:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 23:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

Fatigue

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:44:40
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 23:00:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 23:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:44:58
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 23:00:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 23:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:01
DataPoint Un-verified.	Nick Bart (b) (4)	13 Nov 2020 23:00:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Nick Bart (b) (4)	13 Nov 2020 23:00:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:08
User entered 'None (None)'	Nick Bart (b) (4)	26 Oct 2020 19:40:37

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 19 (Day 19)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:06
User entered '21 Oct 2020'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:08
User entered '0'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:12
User entered '99'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:15
User entered '98.2' F	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:18
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:19
User entered 'Mild (Mild)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:21
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:22
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:26
User entered 'Mild (Mild)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:33
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:34
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:38
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:40
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:41
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:42
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:44
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:45
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:47
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:48
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:49
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:02:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 20 (Day 20)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:53
User entered '22 Oct 2020'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:45:58
User entered '0'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:00
User entered '99'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:01
User entered '98.5' F	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:03
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:05
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:06
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:08
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:10
User entered 'Mild (Mild)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:12
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:13
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:15
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:17
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:18
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:19
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:21
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:23
User entered 'Mild (Mild)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:24
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:26
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:29
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:03:32

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 21 (Day 21)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:32
User entered '23 Oct 2020'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:36
User entered '0'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:38
User entered '99'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:46
User entered '97.8' F	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:50
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:51
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:53
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:54
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:56
User entered 'Mild (Mild)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:57
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:46:58
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:01
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:00
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:02
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:04
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:05
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:06
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:08
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:09
User entered 'Mild (Mild)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:10
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:04:09

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 22 (Day 22)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:17
User entered '24 Oct 2020'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:18
User entered '0'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:20
User entered '99'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:23
User entered '97.9' F	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:24
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:28
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:30
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:32
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:34
User entered 'Mild (Mild)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:55
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:56
User entered 'Not Done (Not Done)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:57
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:59
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:00
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:02
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:03
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:05
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:06
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:08
User entered 'Mild (Mild)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:09
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:01

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
User entered 'Day 23 (Day 23)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:17
User entered '25 Oct 2020'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:19
User entered '0'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:20
User entered '99'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '%'	System	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:23
User entered '97.9' F	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:24
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:26
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:28
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:29
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:31
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:58:08
User closed query 'Muscle ache and body ache not present in source on 25Oct20. Please either update source or EDC.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:58:03
Query 'Muscle ache and body ache not present in source on 25Oct20. Please either update source or EDC.' answered with 'EDC updated to reflect Myalgia not collected' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 17:12:05
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:10:42
User opened query 'Muscle ache and body ache not present in source on 25Oct20. Please either update source or EDC.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:49:55
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:42
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:32
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

Body Aches

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Muscle ache and body ache not present in source on 25Oct20. Please either update source or EDC.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:58:10
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:58:06
Query 'Muscle ache and body ache not present in source on 25Oct20. Please either update source or EDC.' answered with 'EDC updated to reflect Body Aches not collected' (Site from CRA).	Nick Bart (b) (4)	02 Dec 2020 17:12:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:10:42
User opened query 'Muscle ache and body ache not present in source on 25Oct20. Please either update source or EDC.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:50:00
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:33
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:35
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:39
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:48:38
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:02
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:03
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:04
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:06
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:07
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:33:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:02:33
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:35
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:22
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:08
User entered 'None (None)'	Nick Bart (b) (4)	13 Nov 2020 23:05:52

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:33:44

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:50
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:29
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:45:53
User entered '08 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:32:26

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:33:44

[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 15:03:50
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:29
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:45:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:32:26

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:33:44

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 15:03:50
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:29
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:45:59
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)	15 Oct 2020 13:39:21
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 'will do' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 19:32:51
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	14 Oct 2020 19:32:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:32:26

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:33:44

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:50
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:29
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
Query 'Per GCL Lab Recon: Saliva: Samples dated 07OCT2020 for COVID PCR Saliva is reported in PPD central lab, however sample details are missing in EDC. Please complete, thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 04:44:42
User opened query 'Per GCL Lab Recon: Saliva: Samples dated 07OCT2020 for COVID PCR Saliva is reported in PPD central lab, however sample details are missing in EDC. Please complete, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:18:51
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:43:01
User closed query 'Please verify as central lab has results from illness Day 1 collected on 08Oct2020' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:42:55
Query 'Please verify as central lab has results from illness Day 1 collected on 08Oct2020' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:04:59
User entered '08 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:04:26
User opened query 'Please verify as central lab has results from illness Day 1 collected on 08Oct2020' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:08:54
Query 'Please provide source.' canceled (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:08:44
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:46:14
User entered '05 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:32:26

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:33:44

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:50
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:29
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:46:18
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	14 Oct 2020 19:32:26

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:33:44

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:50
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:29
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:46:19
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:32:26

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:33:44

[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 15:03:50
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:29
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:43:45
User closed query 'Please reconcile as central result is present from illness visit. This should be NO and next two fields blank if central result collected' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:43:33
Query 'Please reconcile as central result is present from illness visit. This should be NO and next two fields blank if central result collected' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 16:05:05
DataPoint Un-verified.	Nick Bart (b) (4)	10 Nov 2020 16:04:54
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:04:54
User opened query 'Please reconcile as central result is present from illness visit. This should be NO and next two fields blank if central result collected' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:09:13
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:46:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:32:26

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:33:44

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:50
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:29
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:43:49
DataPoint Un-verified.	Nick Bart (b) (4)	10 Nov 2020 16:04:54
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:04:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:46:26
User entered 'Unknown location (COVID19 test done with her PCP)'	(b) (4), (b) (6)	14 Oct 2020 19:32:26

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:33:44

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:50
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:29
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:44:02
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:04:54
Query 'Per previous response location is unknown, but response to question is Lab is CLIA Certified. Please provide source and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:09:26
User opened query 'Per previous response location is unknown, but response to question is Lab is CLIA Certified. Please provide source and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:36:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:32:26

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:33:44

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:50
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:29
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	14 Oct 2020 19:32:26

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 08:39:50
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:48:10
User closed query 'Please enter as unknown since not documented in source.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:48:07
Query 'Data is required. Please complete.' answered with 'Unknown per previous query request' (Site from System).	Nick Bart (b) (4)	21 Dec 2020 20:02:55
Query 'Please enter as unknown since not documented in source.' answered with 'UNK' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:02:33
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 20:02:28
User entered empty; reason for change New Information	Nick Bart (b) (4)	21 Dec 2020 20:02:28
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:02
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User opened query 'Please enter as unknown since not documented in source.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 21:37:28
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

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 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:36:04
User closed query 'Please enter as unknown since not documented in source.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:36:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Dec 2020 08:40:09
Query 'Data is required. Please complete.' answered with 'Unknown' (Site from System).	Nick Bart (b) (4)	21 Dec 2020 20:03:06
Query 'Please enter as unknown since not documented in source.' answered with 'Unknown per previous query request' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:03:03
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 20:02:28
User entered empty; reason for change New Information	Nick Bart (b) (4)	21 Dec 2020 20:02:28
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 21:38:07
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User opened query 'Please enter as unknown since not documented in source.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 21:37:37
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

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 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User closed query ' Per CDM: It appears O2 Saturation is recorded as Yes with dates of 09OCT - 12OCT and Saturation of 95% yet Days 7 (92%), Day 8 (93%) and Day 9 (89%) are present on Symptom Log which are $\leq$ 93%. Please review and clarify or update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 11:49:31
Query ' Per CDM: It appears O2 Saturation is recorded as Yes with dates of 09OCT - 12OCT and Saturation of 95% yet Days 7 (92%), Day 8 (93%) and Day 9 (89%) are present on Symptom Log which are $\leq$ 93%. Please review and clarify or update accordingly.' answered with 'Updated to 09-11 Oct 2020.' (Site from DM).	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 19:41:38
User opened query ' Per CDM: It appears O2 Saturation is recorded as Yes with dates of 09OCT - 12OCT and Saturation of 95% yet Days 7 (92%), Day 8 (93%) and Day 9 (89%) are present on Symptom Log which are $\leq$ 93%. Please review and clarify or update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 18:49:01
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'Yes (Y)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered '09 Oct 2020'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:31:48
DataPoint Un-verified.	Atanas Filev (b) (4)	10 Feb 2021 19:41:26
User entered '11 Oct 2020' reason for change: Data Entry Error	Atanas Filev (b) (4)	10 Feb 2021 19:41:26
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered '12 Oct 2020'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:31:51
DataPoint Un-verified.	Atanas Filev (b) (4)	10 Feb 2021 19:41:26
User entered '89' reason for change: Data Entry Error	Atanas Filev (b) (4)	10 Feb 2021 19:41:26
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered '95'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User closed query 'PER CDM: Re-Query: Please consider entering ND if the procedure was not performed. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 06:52:48
Query 'PER CDM: Re-Query: Please consider entering ND if the procedure was not performed. Thank you. ' answered with 'ND is recorded below' (Site from DM).	Nick Bart (b) (4)	21 Dec 2020 20:01:45
User opened query 'PER CDM: Re-Query: Please consider entering ND if the procedure was not performed. Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 13:40:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Dec 2020 13:40:16
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
Query 'Data is required. Please complete.' answered with 'Unknown' (Site from System).	Nick Bart (b) (4)	02 Dec 2020 21:29:00
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 21:28:50
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered missing code ND - Not Done.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User closed query 'Per CDM: Re-Query: Per response 'Data added per CRA request'. However, as per CRF it says if yes for Respiratory failure and ARDS, then only ventilator support data should be recorded. Here it was recorded as No. Hence, please consider removing data for ventilator support if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:59:44
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
Query 'Per CDM: Re-Query: Per response 'Data added per CRA request'. However, as per CRF it says if yes for Respiratory failure and ARDS, then only ventilator support data should be recorded. Here it was recorded as No. Hence, please consider removing data for ventilator support if appropriate. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:27:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:25:47
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 15:17:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 15:17:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:17:43
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 15:17:31
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 15:17:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:17:31

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
User opened query 'Per CDM: Re-Query: Per response 'Data added per CRA request'. However, as per CRF it says if yes for Respiratory failure and ARDS, then only ventilator support data should be recorded. Here it was recorded as No. Hence, please consider removing data for ventilator support if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 15:58:21
User closed query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is provided for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 15:58:21
Query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is provided for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' answered with 'Data added per CRA request' (Site from DM).	Nick Bart (b) (4)	02 Mar 2021 16:54:42
User opened query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is provided for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 22:36:13
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 21:29:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 21:29:15
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 21:29:15
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 21:28:50
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:26:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:26:57
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 15:26:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:26:57
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:26:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:26:57
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:46:01
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:26:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:26:57
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:46:03
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 15:26:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:26:57
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:46:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 15:26:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:26:57
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:46:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:26:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:26:57
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:46:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:26:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:26:57
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:46:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:26:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:26:57
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:46:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:26:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:26:57
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:46:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:26:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:26:57
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[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 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 10:33:44

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:02
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:34
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:37:59
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 21:28:50

US3952033

Folder: Covid-19 Assessment 07 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:33:44

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:54
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 20:40:40
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:48
Query 'Per Medical Records on 31Oct20, subject received positive COVID-19 result and had 100.6 fever (symptoms). Please generate new COVID-19 assessment and enter results even if subject did not continue to get evaluated.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:21:46
User opened query 'Per Medical Records on 31Oct20, subject received positive COVID-19 result and had 100.6 fever (symptoms). Please generate new COVID-19 assessment and enter results even if subject did not continue to get evaluated.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:11:07
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 20:54:24
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:37:02
User entered 'No (N)'	Nick Bart (b) (4)	02 Nov 2020 19:23:13

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:33:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:33:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:33:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
User entered '10 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:33:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:33:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:33:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
User entered '12 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:33:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:33:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:33:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:33:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:33:44

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
User closed query 'PER CDM: RE-QUERY: Was Saliva Collected? section was left blank. Please consider checking YES/NO or NA (COVID-19 Negative). Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:57:37
Query 'PER CDM: RE-QUERY: Was Saliva Collected? section was left blank. Please consider checking YES/NO or NA (COVID-19 Negative). Thank you.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	30 Oct 2020 16:02:18
User entered 'Yes (Y)' reason for change: New Information	Nick Bart (b) (4)	30 Oct 2020 16:02:14
User opened query 'PER CDM: RE-QUERY: Was Saliva Collected? section was left blank. Please consider checking YES/NO or NA (COVID-19 Negative). Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:39:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 16:39:44
Query 'Data is required. Please complete.' answered with 'data currently unavailable' (Site from System).	Nick Bart (b) (4)	21 Oct 2020 20:46:29
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 19:43:16
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:33:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
User entered '16 Oct 2020' reason for change: New Information	Nick Bart (b) (4)	30 Oct 2020 16:02:14
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:33:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:33:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
User closed query 'PER CDM: RE-QUERY: Was Saliva Collected? section was left blank. Please consider checking YES/NO or NA (COVID-19 Negative). Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:57:57
Query 'PER CDM: RE-QUERY: Was Saliva Collected? section was left blank. Please consider checking YES/NO or NA (COVID-19 Negative). Thank you.' answered with 'updatefd' (Site from DM).	Nick Bart (b) (4)	30 Oct 2020 16:02:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4)	30 Oct 2020 16:02:52
User opened query 'PER CDM: RE-QUERY: Was Saliva Collected? section was left blank. Please consider checking YES/NO or NA (COVID-19 Negative). Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:40:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 16:39:56
Query 'Data is required. Please complete.' answered with 'data currently unavailable' (Site from System).	Nick Bart (b) (4)	21 Oct 2020 20:46:39
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 19:43:16
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:33:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
User entered '21 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	30 Oct 2020 16:02:52
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:33:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:33:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4)	30 Oct 2020 16:03:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 16:40:21
Query 'Data is required. Please complete.' answered with 'data currently unavailable' (Site from System).	Nick Bart (b) (4)	21 Oct 2020 20:46:45
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 19:43:16
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:33:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
User entered '28 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	30 Oct 2020 16:03:11
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:33:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:33:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per GCL Lab Recon: Saliva: Samples dated 04NOV2020 for Day 28 is reported under Illness visit in EDC, however same is reported for Unscheduled visit in PPD central lab. Please confirm the correct visit, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 11:42:58
Query 'Per GCL Lab Recon: Saliva: Samples dated 04NOV2020 for Day 28 is reported under Illness visit in EDC, however same is reported for Unscheduled visit in PPD central lab. Please confirm the correct visit, Thank you.' answered with 'Unscheduled Kit was used, not an Unscheduled Sample. Revision present in source' (Site from DM).	Nick Bart (b) (4)	21 Dec 2020 20:15:56
User opened query 'Per GCL Lab Recon: Saliva: Samples dated 04NOV2020 for Day 28 is reported under Illness visit in EDC, however same is reported for Unscheduled visit in PPD central lab. Please confirm the correct visit, Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 05:05:43
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:46:25
User entered 'Yes (Y)' reason for change: New Information	Nick Bart (b) (4)	10 Nov 2020 16:31:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 16:40:25
Query 'Data is required. Please complete.' answered with 'data currently unavailable' (Site from System).	Nick Bart (b) (4)	21 Oct 2020 20:46:51
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 19:43:16
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:33:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:46:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04Nov2020 is recorded as Illness Visit Day28 in EDC, however the sample is reported under COVID PCR Saliva visit in PPD Central lab. Please confirm the correct Visit and update if applicable, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 04:40:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04Nov2020 is recorded as Illness Visit Day28 in EDC, however the sample is reported under COVID PCR Saliva visit in PPD Central lab. Please confirm the correct Visit and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:47:32
User entered '04 Nov 2020' reason for change: New Information	Nick Bart (b) (4)	10 Nov 2020 16:31:13
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:43:16

US3952033

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16OCT2020 and 21OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 06:39:44
User closed query 'Per CDM: it appears there is a record for Saliva sample collection with date of 21OCT2020. Please review source and complete a Convalescence Visit Day 28 if applicable.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:31:01
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16OCT2020 and 21OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you.' answered with 'Records present under Saliva Collection eCRF' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 16:35:46
Query 'Per CDM: it appears there is a record for Saliva sample collection with date of 21OCT2020. Please review source and complete a Convalescence Visit Day 28 if applicable.' answered with 'Day 28 Convalescence Visit completed' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 16:34:40
User opened query 'Per CDM: it appears there is a record for Saliva sample collection with date of 21OCT2020. Please review source and complete a Convalescence Visit Day 28 if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:41:40
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16OCT2020 and 21OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 09:35:59

US3952033

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:54:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:39:13

US3952033

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:54:33
User entered '08 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:39:13

US3952033

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[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 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:54:33
User entered 'Home (Home)'	(b) (4), (b) (6)	14 Oct 2020 19:39:13

US3952033

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered 'SICKD1'	System	14 Oct 2020 19:39:13

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:53:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:53:32
User entered '08 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:53:32
User entered '10:10'	(b) (4), (b) (6)	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '08 Oct 2020 10:10'	System	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:53:32
User closed query ' PER CDM: Re-Query: Please consider entering ND if Height and Weight were not performed. Thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:10:30
Query ' PER CDM: Re-Query: Please consider entering ND if Height and Weight were not performed. Thank you. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	21 Oct 2020 20:48:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	21 Oct 2020 20:48:05
User opened query ' PER CDM: Re-Query: Please consider entering ND if Height and Weight were not performed. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 13:28:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 13:27:40
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 19:40:29
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 19:40:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:40:10
DataPoint set to visible.	System	14 Oct 2020 19:39:13

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:53:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	21 Oct 2020 20:48:05
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 13:27:46
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 19:40:36
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 19:40:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:40:10
DataPoint set to visible.	System	14 Oct 2020 19:39:13

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:53:11
Query 'Per Illness visit Day 1, this is documented in Fahrenheit. Please update.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:53:04
User opened query 'Per Illness visit Day 1, this is documented in Fahrenheit. Please update.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:52:27
User entered '37.5' C	(b) (4), (b) (6)	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:52:42
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:52:45
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:53:15
User entered '83'	(b) (4), (b) (6)	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered 'bpm'	System	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'PER CDM: PER CCG V2.0 Page 50, Respiratory Rate: 17-20 breaths per minute (breaths/min) is clinical abnormal Mild (Grade 1). However, participant is not recorded as at risk. Please review and provide, reconcile, or clarification. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:23:28
Query 'PER CDM: PER CCG V2.0 Page 50, Respiratory Rate: 17-20 breaths per minute (breaths/min) is clinical abnormal Mild (Grade 1). However, participant is not recorded as at risk. Please review and provide, reconcile, or clarification. Thank you.' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 19:53:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:53:17
User opened query 'PER CDM: PER CCG V2.0 Page 50, Respiratory Rate: 17-20 breaths per minute (breaths/min) is clinical abnormal Mild (Grade 1). However, participant is not recorded as at risk. Please review and provide, reconcile, or clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:45:51
User entered '20'	(b) (4), (b) (6)	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered 'breaths/min'	System	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:53:23
User entered '136'	(b) (4), (b) (6)	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered 'mmHg'	System	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:53:25
User entered '83'	(b) (4), (b) (6)	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered 'mmHg'	System	14 Oct 2020 19:40:10

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:33:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
Protocol deviation 'Per protocol, physical exam is required for Day 1 of Convalescent period.'	(b) (4)	17 Nov 2020 14:07:04
inactivated.	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:50:42
Protocol deviation created: Per protocol, physical exam is required for Day 1 of Convalescent period.	(b) (4), (b) (6)	29 Oct 2020 19:50:40
Class: Incl/Excl Criteria not met Code: Deviation.		
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 19:40:50

US3952033

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:33:44

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:50:42
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:40:50

US3952033

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 10:33:44

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
Query 'Per GCL Lab Reconciliation: it appears PPD Central lab has SARS-CoV-2 serum sample with date 04NOV2020 under illness visit; however, there is no record in EDC. Please reconcile' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 06:18:39
User opened query 'Per GCL Lab Reconciliation: it appears PPD Central lab has SARS-CoV-2 serum sample with date 04NOV2020 under illness visit; however, there is no record in EDC. Please reconcile' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 10:35:56
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:50:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:41:05

US3952033

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 10:33:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:50:55
User entered '08 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:41:05

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:04
User entered 'Yes (Y)'	Nick Bart (b) (4)	10 Nov 2020 16:31:47

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:04
User entered '04 Nov 2020'	Nick Bart (b) (4)	10 Nov 2020 16:31:47

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[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 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:04
User entered 'Clinic (Clinic)'	Nick Bart (b) (4)	10 Nov 2020 16:31:47

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered 'SICKD28'	System	10 Nov 2020 16:31:47

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:59
User entered 'Yes (Y)'	Nick Bart (b) (4)	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:59
User entered '04 Nov 2020'	Nick Bart (b) (4)	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:48:40
User closed query 'Per Convalescent visit source from 4Nov20, subject was assessed at 13:34.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:48:37
Query 'Per Convalescent visit source from 4Nov20, subject was assessed at 13:34.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 20:00:54
User entered '13:34' reason for change: Data Entry Error	Nick Bart (b) (4)	21 Dec 2020 20:00:51
User opened query 'Per Convalescent visit source from 4Nov20, subject was assessed at 13:34.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 20:41:43
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:40:59
User entered '14:17'	Nick Bart (b) (4)	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '04 Nov 2020 13:34'	System	21 Dec 2020 20:00:51
User entered '04 Nov 2020 14:17'	System	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:59
User entered '65.0' in	Nick Bart (b) (4)	10 Nov 2020 16:32:53
DataPoint set to visible.	System	10 Nov 2020 16:31:47

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:59
User entered '282.5' lb	Nick Bart (b) (4)	10 Nov 2020 16:32:53
DataPoint set to visible.	System	10 Nov 2020 16:31:47

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:59
User entered '36.9' C	Nick Bart (b) (4)	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:59
User entered 'Oral (Oral)'	Nick Bart (b) (4)	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:59
User entered empty.	Nick Bart (b) (4)	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:59
User entered '76'	Nick Bart (b) (4)	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered 'bpm'	System	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:59
User entered '16'	Nick Bart (b) (4)	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered 'breaths/min'	System	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:59
User entered '130'	Nick Bart (b) (4)	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered 'mmHg'	System	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:40:59
User entered '82'	Nick Bart (b) (4)	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered 'mmHg'	System	10 Nov 2020 16:32:53

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:33:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:42:42
User entered 'Yes (Y)'	Nick Bart (b) (4)	10 Nov 2020 16:33:40

US3952033

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:33:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:42:42
User entered '04 Nov 2020'	Nick Bart (b) (4)	10 Nov 2020 16:33:40

US3952033

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 10:33:44

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 NOV 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in Unscheduled visit in GCL. Please Reconcile, else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 06:18:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:42:49
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 NOV 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in Unscheduled visit in GCL. Please Reconcile, else clarify. Thank you.' answered with 'No Unscheduled Visit present for date 04Nov2020' (Site from DM).	Nick Bart (b) (4)	02 Dec 2020 17:16:16
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 NOV 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in Unscheduled visit in GCL. Please Reconcile, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:18:34
User entered 'Yes (Y)'	Nick Bart (b) (4)	10 Nov 2020 16:33:55

US3952033

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 10:33:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:42:49
User entered '04 Nov 2020'	Nick Bart (b) (4)	10 Nov 2020 16:33:55

US3952033

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

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:34
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:20:32

US3952033

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

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:34
User entered '14 Jan 2021'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:20:32

US3952033

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

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[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 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:34
User entered 'Clinic (Clinic)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:20:32

US3952033

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

Form: Visit Date

Generated On: 10 Jun 2021 10:33:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered 'UNBLND_DECIDE'	System	10 Feb 2021 18:20:32

US3952033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:33:44

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:07:34
User entered '14 Jan 2021'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:21:18

US3952033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:33:44

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:24:23

US3952033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:33:44

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:07:38
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:21:18

US3952033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:33:44

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:24:23

US3952033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:33:44

[Date of unblinding \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:07:41
User entered '14 Jan 2021'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:21:18

US3952033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:33:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:07:43
User entered 'Placebo (Placebo)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:21:18

US3952033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:33:44

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:07:45
User entered 'Placebo (Placebo)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:21:18

US3952033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:33:44

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:07:48
User entered 'Not Administered (NA)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:21:18

US3952033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:33:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:13:08
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Mar 2021 16:55:17
User closed query "Will participant receive mRNA-1273?' is missing. Please reconcile.' (Site from System).	System	02 Mar 2021 16:54:55
Query "Will participant receive mRNA-1273?' is missing. Please reconcile.' answered by data change (Site from System).	System	02 Mar 2021 16:54:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Mar 2021 16:54:55
User opened query "Will participant receive mRNA-1273?' is missing. Please reconcile.' (Site from System).	System	10 Feb 2021 18:21:18
User entered empty.	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:21:18

US3952033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:33:44

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	10 Feb 2021 18:21:18

US3952033

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

Form: Unblinding

Generated On: 10 Jun 2021 10:33:44

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	02 Mar 2021 16:55:17
User entered '1'	System	02 Mar 2021 16:54:55
User entered empty.	System	10 Feb 2021 18:21:18

US3952033

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:08:35
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:21:51

US3952033

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:08:35
User entered '14 Jan 2021'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:21:51

US3952033

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:08:35
User entered '17:07'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:21:51

US3952033

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:33:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '14 Jan 2021 17:07'	System	10 Feb 2021 18:21:51

US3952033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:33:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:08:50
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:22:01

US3952033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:08:50
User entered '14 Jan 2021'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:22:01

US3952033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:33:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:08:50
User entered '17:08'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:22:01

US3952033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:33:44

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '14 Jan 2021 17:08'	System	10 Feb 2021 18:22:01

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:33:44

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:00:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 13:44:56
User closed query 'Per CDM: Please consider removing data from this visit as it appears to be a duplicate of the Illness Visit.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:44:54
Query 'Data is required. Please complete.' answered with 'duplicate data removed' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 17:05:46
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:05:37
DataPoint Un-verified.	Nick Bart (b) (4)	10 Nov 2020 17:05:37
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 17:05:37
Query 'Per CDM: Please consider removing data from this visit as it appears to be a duplicate of the Illness Visit.' answered with 'removed' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 17:05:27
User opened query 'Per CDM: Please consider removing data from this visit as it appears to be a duplicate of the Illness Visit.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 17:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:29:17
User entered '02 Sep 2020'	Nick Bart (b) (4)	16 Sep 2020 16:12:43

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:33:44

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:17
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:12:43

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:33:44

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:00:34
DataPoint Un-verified.	Nick Bart (b) (4)	10 Nov 2020 17:05:37
User entered '0' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 17:05:37
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:29:17
User entered '1'	Nick Bart (b) (4)	16 Sep 2020 16:12:43

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:33:44

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:17
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:12:43

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 10:33:44

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:17
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:12:43

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:47
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:47
User entered '02 Sep 2020'	Nick Bart (b) (4)	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:47
User entered '14:01'	Nick Bart (b) (4)	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered '02 Sep 2020 14:01'	System	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:47
User entered '37.3' C	Nick Bart (b) (4)	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:47
User entered 'Oral (Oral)'	Nick Bart (b) (4)	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:47
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:00:14
User closed query 'PER CDM: Please record the data for this section, otherwise enter ND. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:21:16
Query 'PER CDM: Please record the data for this section, otherwise enter ND. Thank you.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 17:06:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 17:06:13
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 20:29:52
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:29:47
User opened query 'PER CDM: Please record the data for this section, otherwise enter ND. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:28:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 13:27:16
Query 'Data is required. Please provide.' answered with 'not repeated' (Site from System).	Nick Bart (b) (4)	16 Sep 2020 16:13:23
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:13:18
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'bpm'	System	10 Nov 2020 17:06:13
User entered empty.	System	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:00:17
User closed query 'PER CDM: Please record the data for this section, otherwise enter ND. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:21:24
Query 'PER CDM: Please record the data for this section, otherwise enter ND. Thank you.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 17:06:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 17:06:13
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 20:29:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:29:47
User opened query 'PER CDM: Please record the data for this section, otherwise enter ND. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:28:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 13:27:11
Query 'Data is required. Please provide.' answered with 'not repeated' (Site from System).	Nick Bart (b) (4)	16 Sep 2020 16:13:35
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 16:13:18
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'breaths/min'	System	10 Nov 2020 17:06:13
User entered empty.	System	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:47
User entered '148'	Nick Bart (b) (4)	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'mmHg'	System	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:11:11
User closed query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure $\geq$ 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 10:26:04
Query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure $\geq$ 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	02 Dec 2020 17:20:15
User opened query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure $\geq$ 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 03:15:03
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:29:47
User entered '94'	Nick Bart (b) (4)	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15
User entered 'mmHg'	System	16 Sep 2020 16:13:18

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15

US3952033

Folder: Unscheduled 02 Sep 2020

Form: Vital Signs

Generated On: 10 Jun 2021 10:33:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:24:15

US3952033

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:33:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE, JOINT ACHES, MUSCLE ACHES and UNDERARM GLAND SWELLING/TENDERNESS persist beyond Day 7 (start date: Day 8; end date: Day 16). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 11:39:11
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE, JOINT ACHES, MUSCLE ACHES and UNDERARM GLAND SWELLING/TENDERNESS persist beyond Day 7 (start date: Day 8; end date: Day 16). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'Lymphadenopathy under AE. Fatigue, joint aches, and muscle aches are related to PMI (Chronic Pain Syndrome) ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:34:43
User closed query 'Per medical records on 31-Oct-20, subject received CT head which revealed Paget's disorder. Please add to AE log.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 07:16:02
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE, JOINT ACHES, MUSCLE ACHES and UNDERARM GLAND SWELLING/TENDERNESS persist beyond Day 7 (start date: Day 8; end date: Day 16). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:01:36
Query 'Per medical records on 31-Oct-20, subject received CT head which revealed Paget's disorder. Please add to AE log.' answered with 'After a review of the medical records, there is no diagnosis of Paget's disorder noted. ' (Site from CRA).	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 17:58:32
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:03:47

US3952033

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:33:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per medical records on 31-Oct-20, subject received CT head which revealed Paget's disorder. Please add to AE log.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:20:29
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 21:16:57
User signature succeeded.	Mimi Van Der Leden	04 Nov 2020 22:15:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:06:40
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:30:19

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User closed query 'Per MM: please confirm if action taken with IP is correct, per protocol sec 7.1, if the subject diagnosed with 'Acute moderate or severe infection with or without fever at the time of dosing , the participant may be injected at a later date within the time window or discontinued from dosing'. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:47:51
Query 'Per MM: please confirm if action taken with IP is correct, per protocol sec 7.1, if the subject diagnosed with 'Acute moderate or severe infection with or without fever at the time of dosing , the participant may be injected at a later date within the time window or discontinued from dosing'. ' answered with 'confirmed correct' (Site from DM).	Nick Bart (b) (4)	22 Oct 2020 15:20:37
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User opened query 'Per MM: please confirm if action taken with IP is correct, per protocol sec 7.1, if the subject diagnosed with 'Acute moderate or severe infection with or without fever at the time of dosing , the participant may be injected at a later date within the time window or discontinued from dosing'. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:27:29
User closed query 'Per CDM: Please clarify, since Herpes Simplex I is recorded on the Medical History form starting in 1976 and is ongoing. Please clarify if the condition worsened and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:51:57
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex aggravated - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	29 Sep 2020 08:05:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 08:05:45

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please clarify, since Herpes Simplex I is recorded on the Medical History form starting in 1976 and is ongoing. Please clarify if the condition worsened and update as appropriate.'	Atanas Filev (b) (4)	28 Sep 2020 19:52:33
answered with 'Updated AE term to better reflect situation.' (Site from DM).	(b) (4)	
Data point term sent to Coder	System	28 Sep 2020 19:52:03
Coding entries removed.	Atanas Filev (b) (4)	28 Sep 2020 19:52:02
	(b) (4)	
User entered 'HERPES SIMPLEX I Exacerbation'	Atanas Filev (b) (4)	28 Sep 2020 19:52:02
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Please clarify, since Herpes Simplex I is recorded on the Medical History form starting in 1976 and is ongoing. Please clarify if the condition worsened and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:38:09
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type I - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 16:33:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 16:33:40
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 16:33:10
User entered 'herpes simplex i'	Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:58:50
Signature has been broken.	Mimi Van Der Leden	29 Sep 2020 14:51:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Mimi Van Der Leden	29 Sep 2020 14:51:34
User signature succeeded.	(b) (4) Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'No (N)'	Nick Bart	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '07 Sep 2020'	Nick Bart	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	(b) (4)	16 Sep 2020 16:32:42
	Nick Bart (b) (4)	

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:28:52
Signature has been broken.	Nick Bart (b) (4)	22 Oct 2020 15:19:27
User entered 'No (N)' reason for change: Per Query Resolution	Nick Bart (b) (4)	22 Oct 2020 15:19:27
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 20:04:53
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:28:54
User closed query 'Please enter stop date.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 19:37:30
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Oct 2020 15:20:58
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	22 Oct 2020 15:20:58
Query 'Please enter stop date.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	22 Oct 2020 15:20:48
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Oct 2020 15:19:27
Signature has been broken.	Nick Bart (b) (4)	22 Oct 2020 15:19:27
User entered '14 Sep 2020' reason for change: Per Query Resolution	Nick Bart (b) (4)	22 Oct 2020 15:19:27
User opened query 'Please enter stop date.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 20:05:25
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 20:04:54
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	(b) (4) Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	(b) (4)	16 Sep 2020 16:32:42
	Nick Bart (b) (4)	

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:04
User closed query 'Per DM CLR-RQ: Site's response noted. However, grade of the baseline condition is considered as Grade 1/Mild and a worsening event is expected to have a severity that is greater than Grade 1/Mild. Please review and update severity as appropriate. Otherwise, provide further clarification.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:42:04
Query 'Per DM CLR-RQ: Site's response noted. However, grade of the baseline condition is considered as Grade 1/Mild and a worsening event is expected to have a severity that is greater than Grade 1/Mild. Please review and update severity as appropriate. Otherwise, provide further clarification.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 19:43:31
DataPoint Un-verified.	Nick Bart (b) (4)	10 Nov 2020 19:43:27
Signature has been broken.	Nick Bart (b) (4)	10 Nov 2020 19:43:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 19:43:27
User opened query 'Per DM CLR-RQ: Site's response noted. However, grade of the baseline condition is expected to have a severity that is greater than Grade 1/Mild. Please review and update severity as appropriate. Otherwise, provide further clarification.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 00:11:33
User closed query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:48:16

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Severity](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history.' answered with 'mild grading refers to the exacerbation not the condition' (Site from DM). DataPoint Verified.	Nick Bart (b) (4) (b) (4)	22 Oct 2020 15:22:00
	(b) (4), (b) (6) (b) (4)	09 Oct 2020 19:58:50
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	08 Oct 2020 20:37:45
	Mimi Van Der Leden (b) (4)	29 Sep 2020 14:50:59
User entered 'Grade 1/Mild (Grade 1/Mild)'	Nick Bart (b) (4) (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'No (N)'	Nick Bart	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '0'	Nick Bart	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '0'	Nick Bart	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '0'	Nick Bart	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	Nick Bart	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	Nick Bart	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	(b) (4)	16 Sep 2020 16:32:42
	Nick Bart (b) (4)	

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	(b) (4)	16 Sep 2020 16:32:42
	Nick Bart (b) (4)	

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '0'	Nick Bart	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '0'	Nick Bart	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '0'	(b) (4) Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Sep 2020 16:33:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 16:33:26
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Nick Bart (b) (4)	16 Sep 2020 16:33:26
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 16:32:42
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Sep 2020 16:33:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 16:33:26
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Nick Bart (b) (4)	16 Sep 2020 16:33:26
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 16:32:42
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Sep 2020 16:33:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 16:33:26
User entered 'None (NONE)' reason for change: Per Query Resolution	Nick Bart (b) (4)	16 Sep 2020 16:33:26
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 16:32:42
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
Signature has been broken.	(b) (4) Nick Bart (b) (4)	02 Dec 2020 16:46:11
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	16 Sep 2020 16:33:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Sep 2020 16:32:42
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '1' reason for change: Per Query Resolution	(b) (4)	
	Nick Bart (b) (4)	16 Sep 2020 16:33:26
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '0'	Nick Bart	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:17
DataPoint Un-verified.	Nick Bart (b) (4)	22 Oct 2020 15:20:58
Signature has been broken.	Nick Bart (b) (4)	22 Oct 2020 15:20:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Nick Bart (b) (4)	22 Oct 2020 15:20:58
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden (b) (4)	29 Sep 2020 14:50:59
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 16:33:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 16:33:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Per Query Resolution	Nick Bart (b) (4)	16 Sep 2020 16:33:26
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 16:32:42
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	(b) (4)	16 Sep 2020 16:32:42
	Nick Bart (b) (4)	

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	(b) (4)	
	Nick Bart (b) (4)	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '0'	System	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '0'	System	29 Sep 2020 14:51:34
User entered '1'	System	16 Sep 2020 16:32:42

US3952033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:03:15
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:03:13
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:16
User entered 'USA-US215-2020-mRNA-1273-P301000001'	System	29 Sep 2020 14:21:13
User entered 'New'	(b) (4), (b) (6)	29 Sep 2020 14:21:13

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:22:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 11:32:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 11:32:18
Data point term sent to Coder	System	21 Jan 2021 15:59:27
DataPoint Un-verified.	Nick Bart (b) (4)	21 Jan 2021 15:58:27
Coding entries removed.	Nick Bart (b) (4)	21 Jan 2021 15:58:27
Signature has been broken.	Nick Bart (b) (4)	21 Jan 2021 15:58:27
User entered 'gastritis w/ intractable vomiting' reason for change: Data Entry Error	Nick Bart (b) (4)	21 Jan 2021 15:58:27
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden (b) (4)	29 Sep 2020 14:50:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal disorders NEC, PT: Food poisoning, LLT: Food poisoning - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 20:09:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 20:09:39
Data point term sent to Coder	System	28 Sep 2020 20:08:53
User entered 'Food Poisoning'	Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '23 Sep 2020'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:02:01
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). Signature has been broken.	System Atanas Filev (b) (4)	09 Oct 2020 20:22:07 09 Oct 2020 20:22:07
User entered 'No (N)' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:22:07
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Oct 2020 20:20:44
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 20:00:44
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:02:03
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)	12 Oct 2020 14:20:34
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 provided.' (Site from Safety).	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:21:08
Signature has been broken.	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:20:44
User entered '30 Sep 2020' reason for change: New Information	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:20:44
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 20:00:40
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
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)	07 Oct 2020 20:22:29
User signature succeeded.	Mimi Van Der Leden (b) (4)	29 Sep 2020 14:50:59
User entered empty.	Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:05:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 18:22:28
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	Atanas Filev (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User closed query 'PV Query: As event of food poisoning required hospitalization, please confirm intensity of grade 3.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 12:37:42
Query 'PV Query: As event of food poisoning required hospitalization, please confirm intensity of grade 3.' answered with 'Severity confirmed' (Site from Safety).	Nick Bart (b) (4)	02 Dec 2020 16:32:42
User opened query 'PV Query: As event of food poisoning required hospitalization, please confirm intensity of grade 3.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 23:43:59
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'Grade 3/Severe (Grade 3/Severe)'	Atanas Filev (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '0'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '0'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 14:55:39
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Pending hospital records. ' (Site from System).	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	Atanas Filev (b) (4)	28 Sep 2020 20:09:34
User entered '1'	(b) (4)	
	System	28 Sep 2020 20:08:43
	Atanas Filev (b) (4)	28 Sep 2020 20:08:43
	(b) (4)	

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User closed query 'Per medical records, subject was admitted on 26Sep20. Please reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:17:19
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:17:15
Query 'Per medical records, subject was admitted on 26Sep20. Please reconcile.' answered with 'Updated.' (Site from CRA).	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:03:22
Signature has been broken.	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:03:14
User entered '26 Sep 2020' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:03:14
User opened query 'Per medical records, subject was admitted on 26Sep20. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 18:27:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 18:26:43
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 18:26:42
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 18:26:39
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden (b) (4)	29 Sep 2020 14:50:59
User entered '23 Sep 2020'	Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:02:12
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:20:39
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Entered. ' (Site from Safety).	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:21:25
DataPoint Un-verified.	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:20:44
Signature has been broken.	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:20:44
User entered '30 Sep 2020' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:20:44
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:22:42
User signature succeeded.	Mimi Van Der Leden (b) (4)	29 Sep 2020 14:50:59
User entered empty.	Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:06:06
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:28:28
Query 'Please provide source.' answered with 'Medical records pending, will update when data is available' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 19:39:03
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 20:08:56
User closed query ' PER CDM: Re Query: Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:43:42
Query ' PER CDM: Re Query: Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No. Thank you.' answered with 'Entered. ' (Site from DM).	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:21:26
DataPoint Un-verified.	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:20:44
Signature has been broken.	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:20:44
User entered 'No (N)' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:20:44
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User opened query ' PER CDM: Re Query: Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:55:29

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). User signature succeeded.	(b) (4), (b) (6) Mimi Van Der Leden (b) (4)	29 Sep 2020 14:54:46 29 Sep 2020 14:50:59
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'Pending hospital records. ' (Site from System).	Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:09:37
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	28 Sep 2020 20:08:43
User entered 'Unknown (UNK)'	Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '0'	Atanas Filev (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '0'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '0'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'Not Related (NOT RELATED)'	Atanas Filev	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'Not Related (NOT RELATED)'	Atanas Filev	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'None (NONE)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:17:31
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). DataPoint Un-verified.	Atanas Filev (b) (4)	10 Feb 2021 18:05:20
Signature has been broken.	(b) (4) Atanas Filev (b) (4)	10 Feb 2021 18:05:20
User entered '0' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	10 Feb 2021 18:05:20
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). User closed query 'Per DM CLR: Re-Query: Per previous response ' Medical records pending for information. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given' (Site from DM).	System (b) (4), (b) (6)	10 Feb 2021 18:05:03 12 Nov 2020 08:37:09
Query 'Per DM CLR: Re-Query: Per previous response ' Medical records pending for information. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given' answered with 'Site does not have required data until medical records are received. At this time, no queries can be resolved for this SAE.' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 19:41:39

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Re-Query: Per previous response ' Medical records pending for information. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:15:58
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:15:58
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'Medical Records pending for information. ' (Site from DM).	Atanas Filev (b) (4)	09 Oct 2020 20:19:53
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 20:38:13
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered '1'	(b) (4) Atanas Filev (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 18:23:02
User closed query 'Per source, this is incorrect.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:28:38
Query 'Per source, this is incorrect.' answered with 'Per source, "Unknown" is checked as medical records have not been received yet.' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 19:42:03
User opened query 'Per source, this is incorrect.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 14:34:37
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 14:33:48
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden (b) (4)	29 Sep 2020 14:50:59
User entered '0'	Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User closed query 'Per DM CLR: OTHER ACTION TAKEN = Con Procedure, however there is no 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) (4), (b) (6)	07 Apr 2021 07:44:11
Query 'Per DM CLR: OTHER ACTION TAKEN = Con Procedure, however there is no 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 'Updated Con Procedure' (Site from DM).	Atanas Filev (b) (4) (b) (4)	06 Apr 2021 23:10:14
User opened query 'Per DM CLR: OTHER ACTION TAKEN = Con Procedure, however there is no 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)	12 Mar 2021 07:52:55
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:17:35
DataPoint Un-verified.	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:05:03
Signature has been broken.	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:05:03
User entered '1' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:05:03
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden (b) (4)	29 Sep 2020 14:50:59
User entered '0'	Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:09:03
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:20:46
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Provided' (Site from Safety).	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:21:39
Signature has been broken.	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:20:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:20:44
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 19:59:12
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:23:15
User signature succeeded.	Mimi Van Der Leden (b) (4)	29 Sep 2020 14:50:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:33:48
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:26:26
User closed query 'Per DM CLR: Narrative indicates that the subject was diagnosed with Preseptal Orbital Cellulitis. However, there is no corresponding AE record that match the information. Please review and update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 11:39:41
User closed query 'Per DM CLR: Narrative indicates that the subject underwent EGD, CT Scan of Sinuses with Contrast and CT Scan of Neck with Contrast. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 11:39:36
User closed query 'Per DM CLR: Narrative indicates that the subject was given Compazine, Pantoprazole, Moxifloxacin, Vancomycin and Omeprazole. However, there are no corresponding ConMed record that match these medications. Please review and update to record the medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 11:39:30
Query 'Per DM CLR: Narrative indicates that the subject was given Compazine, Pantoprazole, Moxifloxacin, Vancomycin and Omeprazole. However, there are no corresponding ConMed record that match these medications. Please review and update to record the medications as appropriate. Otherwise, clarify.' answered with 'Med list updated ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 22:52:09

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that the subject was diagnosed with Preseptal Orbital Cellulitis. However, there is no corresponding AE record that match the information. Please review and update to record the corresponding AE as appropriate. Otherwise, clarify.' answered with 'Preseptal orbital cellulitis is a recurrent complication of subject chronic sinusitis' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:41:13
Query 'Per DM CLR: Narrative indicates that the subject underwent EGD, CT Scan of Sinuses with Contrast and CT Scan of Neck with Contrast. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures as appropriate. Otherwise, clarify.' answered with 'Present in CP folder' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:21:02
User opened query 'Per DM CLR: Narrative indicates that the subject was diagnosed with Preseptal Orbital Cellulitis. However, there is no corresponding AE record that match the information. Please review and update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:32:15
User opened query 'Per DM CLR: Narrative indicates that the subject underwent EGD, CT Scan of Sinuses with Contrast and CT Scan of Neck with Contrast. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:31:45
User opened query 'Per DM CLR: Narrative indicates that the subject was given Compazine, Pantoprazole, Moxifloxacin, Vancomycin and Omeprazole. However, there are no corresponding ConMed record that match these medications. Please review and update to record the medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:30:47
User closed query 'PV Query: Please consider whether the intractable vomiting reported with gastritis meets SAE criteria and update report if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:53:17

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider whether the preseptal orbital cellulitis diagnosed during the hospitalization meets SAE criteria (i.e. prolongation of hospitalization) and update report if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:53:13
User closed query 'Please add CT Neck with Contrast to Concomitant procedures.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:17:48
Query 'Please add CT Neck with Contrast to Concomitant procedures.' answered with 'Procedure added.' (Site from CRA).	Atanas Filev (b) (4)	10 Feb 2021 18:14:14
Query 'PV Query: Please consider whether the intractable vomiting reported with gastritis meets SAE criteria and update report if applicable.' answered with 'Nausea and vomiting are a symptom of gastritis, not a separate AE.' (Site from Safety).	Atanas Filev (b) (4)	10 Feb 2021 18:02:44
Query 'PV Query: Please consider whether the preseptal orbital cellulitis diagnosed during the hospitalization meets SAE criteria (i.e. prolongation of hospitalization) and update report if applicable.' answered with 'Orbital Cellulitis is part of subject's PMH (Chronic Sinusitis). Recurrences are natural course (common) for her. Did not prolong hospitalization. Managed as an outpatient.' (Site from Safety).	Atanas Filev (b) (4)	10 Feb 2021 18:02:04
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:06:17
User opened query 'Please add CT Neck with Contrast to Concomitant procedures.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 18:29:02
User opened query 'PV Query: Please consider whether the intractable vomiting reported with gastritis meets SAE criteria and update report if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 12:44:32
User opened query 'PV Query: Please consider whether the preseptal orbital cellulitis diagnosed during the hospitalization meets SAE criteria (i.e. prolongation of hospitalization) and update report if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 12:44:25

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. stool culture, CBC with differential, stool WBC). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 15:19:55
User closed query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 15:19:54
User closed query 'PV Query: Has the subject had recent treatment with antibiotics, consumption of meats (cooked, uncooked), eggs, seafood, dairy foods and unusual foods?' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 15:19:52
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)	22 Jan 2021 15:19:50
User closed query 'PV Query: Please clarify whether pericarditis treated on 01-NOV-2020, nausea treated on 31-OCT-2020, GERD treated on 01-NOV-2020, and tenderness treated on 02-SEP-2020 meet criteria of AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 15:19:49
Query 'PV Query: Please clarify whether pericarditis treated on 01-NOV-2020, nausea treated on 31-OCT-2020, GERD treated on 01-NOV-2020, and tenderness treated on 02-SEP-2020 meet criteria of AE/SAE.' answered with 'pericarditis already noted as SAE' (Site from Safety).	Mimi Van Der Leden (b) (4)	21 Jan 2021 15:38:12
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 'see narrative; conmeds will be updated' (Site from Safety).	Mimi Van Der Leden (b) (4)	21 Jan 2021 15:31:57

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Has the subject had recent treatment with antibiotics, consumption of meats (cooked, uncooked), eggs, seafood, dairy foods and unusual foods?' answered with 'no' (Site from Safety).	Mimi Van Der Leden (b) (4)	21 Jan 2021 15:31:35
Query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' answered with 'nausea and vomiting' (Site from Safety).	Mimi Van Der Leden (b) (4)	21 Jan 2021 15:31:26
Query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. stool culture, CBC with differential, stool WBC). Please include units and reference ranges if applicable.' answered with 'no relevant diagnostic test results' (Site from Safety).	Mimi Van Der Leden (b) (4)	21 Jan 2021 15:31:19
Signature has been broken.	Mimi Van Der Leden (b) (4)	21 Jan 2021 15:30:25

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTS ADMISSION IN HOSPITAL ON 23 SEP 2020 FOR FOOD POISONING, PER PATIENT REPORT. STILL IN HOSPITAL. WILL FOLLOW APPROPRIATELY AND OBTAIN MEDICAL RECORDS UPON DISCHARGE. SAE UPDATE per Medical Records Clarify Admit Date 26SEP2020 Discharge Date 30SEP2020 Pt presented with intractable nausea and vomiting. Was given compazine along with a clear liquid diet. EGD revealed mild inflammation in stomach and duodenum concerning for gastritis, so pt was started on pantoprazole 40mg daily. Nausea and vomiting resolved with ability to tolerate bland po diet. Pt began having right sided headache with rhinorrhea, pain with extraocular movements, blurry vision, mild erythema and edema. Pt was seen by ENT and ophthalmology who were concerned for the possibility of preseptal sinusitis. Pt was started on po moxifloxacin. CT of sinuses with contrast and CT neck with contrast demonstrated preseptal orbital cellulitis. Pt was discharged with outpatient ENT follow up, in addition to ten day course of po antibiotics. ID evaluated patient on 30Sep2020. Plan was to finish moxifloxacin 400mg daily for total of ten days (finish on 08OCT2020), along with vancomycin 125 mg bid (finish on 11Oct2020) for C Difficile prophylaxis. Pt was given compazine and omeprazole at discharge. Discharged to home on 30SEP2020.'	Mimi Van Der Leden (b) (4)	21 Jan 2021 15:30:25
reason for change: Data Entry Error User opened query 'PV Query: Please clarify whether pericarditis treated on 01-NOV-2020, nausea treated on 31-OCT-2020, GERD treated on 01-NOV-2020, and tenderness treated on 02-SEP-2020 meet criteria of AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 17:21:07

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
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)	17 Nov 2020 23:43:17
User opened query 'PV Query: Has the subject had recent treatment with antibiotics, consumption of meats (cooked, uncooked), eggs, seafood, dairy foods and unusual foods?' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 23:42:42
User opened query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 23:42:17
Query '(AE #2) PV Query: Please provide the signs and symptoms exhibited by the subject.' canceled (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 23:42:06
User opened query '(AE #2) PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 23:42:01
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. stool culture, CBC with differential, stool WBC). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 23:41:43
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)	11 Nov 2020 15:36:04
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. stool culture, CBC with differential, stool WBC). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:35:53

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide additional information regarding the course of the event, including response to treatment and diagnostic test results at event resolution, if available.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:35:39
User closed query 'PV Query: Has the subject had recent treatment with antibiotics, consumption of meats (cooked, uncooked), eggs, seafood, dairy foods and unusual foods?' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:35:07
User closed query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:34:55
Query 'PV Query: Please provide additional information regarding the course of the event, including response to treatment and diagnostic test results at event resolution, if available.' answered with 'Medical records pending, will update when data is available' (Site from Safety).	Nick Bart (b) (4)	10 Nov 2020 19:43:03
Query 'PV Query: Has the subject had recent treatment with antibiotics, consumption of meats (cooked, uncooked), eggs, seafood, dairy foods and unusual foods?' answered with 'Medical records pending, will update when data is available' (Site from Safety).	Nick Bart (b) (4)	10 Nov 2020 19:42:58
Query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' answered with 'Medical records pending, will update when data is available' (Site from Safety).	Nick Bart (b) (4)	10 Nov 2020 19:42:43
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 'will update when MR are received' (Site from Safety).	Nick Bart (b) (4)	10 Nov 2020 19:42:33
Query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. stool culture, CBC with differential, stool WBC). Please include units and reference ranges if applicable.' answered with 'Will provide data if present in medical records' (Site from Safety).	Nick Bart (b) (4)	10 Nov 2020 19:42:22

PRODUCTION RELEASE (v12.003
EAB) (1725)

2458 of 4253

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide additional information regarding the course of the event, including response to treatment and diagnostic test results at event resolution, if available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:57:25
User closed query 'PV Query: Please provide additional information regarding the course of the event, including response to treatment and diagnostic test results at event resolution, if available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:57:25
User opened query 'PV Query: Has the subject had recent treatment with antibiotics, consumption of meats (cooked, uncooked), eggs, seafood, dairy foods and unusual foods?' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:57:18
User closed query 'PV Query: Has the subject had recent treatment with antibiotics, consumption of meats (cooked, uncooked), eggs, seafood, dairy foods and unusual foods?' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:57:18
User opened query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:57:10
User closed query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:57:10
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)	23 Oct 2020 19:56:59
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)	23 Oct 2020 19:56:59

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. stool culture, CBC with differential, stool WBC). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:56:47
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. stool culture, CBC with differential, stool WBC). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:56:47
Query 'PV Query: Please provide additional information regarding the course of the event, including response to treatment and diagnostic test results at event resolution, if available.' answered with 'Will report after discussion with investigator/when data is available in source' (Site from Safety).	Nick Bart (b) (4)	22 Oct 2020 21:08:08
Query 'PV Query: Has the subject had recent treatment with antibiotics, consumption of meats (cooked, uncooked), eggs, seafood, dairy foods and unusual foods? ' answered with 'Information not yet available' (Site from Safety).	Nick Bart (b) (4)	22 Oct 2020 21:07:34
Query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' answered with 'Will update when data available' (Site from Safety).	Nick Bart (b) (4)	22 Oct 2020 21:07:23
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 'Will follow review of records' (Site from Safety).	Nick Bart (b) (4)	22 Oct 2020 21:07:12
Query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. stool culture, CBC with differential, stool WBC). Please include units and reference ranges if applicable.' answered with 'Data to follow receipt of results' (Site from Safety).	Nick Bart (b) (4)	22 Oct 2020 21:06:59

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide additional information regarding the course of the event, including response to treatment and diagnostic test results at event resolution, if available.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 16:19:18
User opened query 'PV Query: Has the subject had recent treatment with antibiotics, consumption of meats (cooked, uncooked), eggs, seafood, dairy foods and unusual foods? ' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 16:14:49
User opened query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 16:14:02
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)	16 Oct 2020 16:13:30
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. stool culture, CBC with differential, stool WBC). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 16:12:28
User closed query 'PV Query: Has the subject had recent treatment with antibiotics, consumption of meats (cooked, uncooked), eggs, seafood, dairy foods and unusual foods?' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:21:02
User closed query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:20:59
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)	12 Oct 2020 14:20:56

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. stool culture, CBC with differential, stool WBC). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:20:52
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 'Medical Records pending. ' (Site from Safety).	Atanas Filev (b) (4)	09 Oct 2020 20:21:55
Query 'PV Query: Has the subject had recent treatment with antibiotics, consumption of meats (cooked, uncooked), eggs, seafood, dairy foods and unusual foods?' answered with 'Medical Records pending. ' (Site from Safety).	Atanas Filev (b) (4)	09 Oct 2020 20:21:52
Query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' answered with 'Medical Records pending. ' (Site from Safety).	Atanas Filev (b) (4)	09 Oct 2020 20:21:50
Query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. stool culture, CBC with differential, stool WBC). Please include units and reference ranges if applicable.' answered with 'Medical Records pending. ' (Site from Safety).	Atanas Filev (b) (4)	09 Oct 2020 20:21:48
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 19:59:42
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:58:50
User opened query 'PV Query: Has the subject had recent treatment with antibiotics, consumption of meats (cooked, uncooked), eggs, seafood, dairy foods and unusual foods?' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:24:11
User opened query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:23:40

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
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)	07 Oct 2020 20:23:29
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. stool culture, CBC with differential, stool WBC). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:22:58
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:50:59
User entered 'Subject reports admission in hospital on 23 Sep 2020 for food poisoning, per patient report. Still in hospital. Will follow appropriately and obtain medical records upon discharge.'	Atanas Filev (b) (4)	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '0'	System	28 Sep 2020 20:08:43

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:15:59
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:16:45
User entered 'USA-US215-2020-mRNA-1273-P301000007'	System	03 Dec 2020 19:16:30
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 19:16:30
Un-reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:15:42
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 19:15:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 19:15:42
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:03:15
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:23:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:00
User entered 'USA-US215-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	12 Oct 2020 14:21:55

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:23:06
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:18:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:18:52
Data point term sent to Coder	System	09 Oct 2020 20:17:30
User entered 'COVID-19 Infection'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:23:08
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:23:14
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:23:18
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User closed query 'PV Query: It was reported that symptoms began on 03 OCT 2020, however the start date of COVID-19 infection was reported as 06 OCT 2020, please consider updating start date of the event to the date that symptoms started.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:29:13
Query 'PV Query: It was reported that symptoms began on 03 OCT 2020, however the start date of COVID-19 infection was reported as 06 OCT 2020, please consider updating start date of the event to the date that symptoms started.' answered with 'Correct as entered. Could not be confirmed related to Covid-19 Infection prior to return of test result.' (Site from Safety).	Nick Bart (b) (4)	21 Dec 2020 19:56:09
User opened query 'PV Query: It was reported that symptoms began on 03 OCT 2020, however the start date of COVID-19 infection was reported as 06 OCT 2020, please consider updating start date of the event to the date that symptoms started.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 21:12:42
User closed query 'PV Query: As the subject had a positive test on 05 Oct 2020. Please consider updating event start from 06 Oct 2020 to 05 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 13:24:12
User closed query 'Per CDM: Start date recorded as 06-OCT-20. However, in symptom log Day 1 was reported as 08-OCT-20. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:33:35
Query 'PV Query: As the subject had a positive test on 05 Oct 2020. Please consider updating event start from 06 Oct 2020 to 05 Oct 2020.' answered with 'Subject's positive test date is 06Oct2020 per progress note dated 08Oct2020. Correct as entered' (Site from Safety).	Nick Bart (b) (4)	02 Dec 2020 16:57:08

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Start date recorded as 06-OCT-20. However, in symptom log Day 1 was reported as 08-OCT-20. Please review and update as appropriate. Thank you. ' answered with '08Oct2020 is when site spoke with subject and was made aware of subject's positive Covid-19 test that was performed while subject was in emergency room. 06Oct2020 is date of Covid positive test' (Site from DM).	Nick Bart (b) (4)	02 Dec 2020 16:55:22
User opened query 'PV Query: As the subject had a positive test on 05 Oct 2020. Please consider updating event start from 06 Oct 2020 to 05 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 23:46:22
User opened query 'Per CDM: Start date recorded as 06-OCT-20. However, in symptom log Day 1 was reported as 08-OCT-20. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:00:29
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:23:20
User entered '06 Oct 2020'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:23:22
User entered empty.	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:30:50
User closed query 'Please confirm' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:30:45
Query 'Please confirm' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 15:44:32
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 15:44:26
User opened query 'Please confirm' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 20:23:33
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:58
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 06:48:41
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)	11 Nov 2020 15:34:02
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Nick Bart (b) (4)	10 Nov 2020 15:46:12
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 15:44:41
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Nov 2020 15:44:26
User entered '25 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 15:44:26
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)	23 Oct 2020 19:56:11
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 Oct 2020 19:56:11

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, end date (dd MMM yyyy)

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.' answered with 'Acknowledged. Data forthcoming' (Site from Safety).	Nick Bart (b) (4)	22 Oct 2020 21:08:39
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)	16 Oct 2020 16:10:58
User entered empty.	Atanas Filev (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:31:02
User entered empty.	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:23:42
User entered 'Grade 3/Severe (Grade 3/Severe)'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:25:42
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4)	16 Oct 2020 20:50:34
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:25:58
User entered '0'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:26:01
User entered '0'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:31:19
User closed query 'PER CDM: RE-QUERY: Response noted. However, kindly considering update the details for Hospital Discharge Date and Admitted to ICU? If appropriate. Thank you. ' (Site from DM). Query 'PER CDM: RE-QUERY: Response noted. However, kindly considering update the details for Hospital Discharge Date and Admitted to ICU? If appropriate. Thank you. ' answered with 'downgraded from SAE to AE' (Site from DM). User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6) Nick Bart (b) (4) Nick Bart (b) (4)	19 Oct 2020 13:43:41 16 Oct 2020 20:52:19 16 Oct 2020 20:50:34
User opened query 'PER CDM: RE-QUERY: Response noted. However, kindly considering update the details for Hospital Discharge Date and Admitted to ICU? If appropriate. Thank you. ' (Site from DM). User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Site pending records. ' (Site from System). User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) Atanas Filev (b) (4) System Atanas Filev (b) (4) (b) (4)	13 Oct 2020 08:37:24 13 Oct 2020 08:37:11 09 Oct 2020 20:17:33 09 Oct 2020 20:16:48 09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:31:23
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	16 Oct 2020 20:50:34
User entered '09 Oct 2020'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:31:25
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:49:28
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'downgraded from SAE to AE' (Site from Safety).	Nick Bart (b) (4)	16 Oct 2020 20:52:17
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 16:11:15
User entered empty.	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:31:28
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	16 Oct 2020 20:50:34
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 08:37:14
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'Pending records. ' (Site from System).	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:17:12
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	09 Oct 2020 20:16:48
User entered 'Unknown (UNK)'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:31:30
User entered empty.	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:31:33
User entered '0'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:31:35
User entered '0'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:31:37
User entered '0' reason for change: Data Entry Error	Nick Bart (b) (4)	16 Oct 2020 20:50:34
User entered '1'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:26:14
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 20:52:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 20:52:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nick Bart (b) (4)	16 Oct 2020 20:52:01
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 20:50:34
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	16 Oct 2020 20:50:34
User entered 'Not Related (NOT RELATED)'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:26:53
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 20:52:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 20:52:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Nick Bart (b) (4)	16 Oct 2020 20:52:01
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 20:50:34
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	16 Oct 2020 20:50:34
User entered 'Not Related (NOT RELATED)'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:43:46
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	03 Dec 2020 13:38:09
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'IP withdrawn due to positive Covid-19 test. On Dosing Discontinuation page, AE and positive Covid test are different selections' (Site from System).	Nick Bart (b) (4)	02 Dec 2020 17:26:28
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	02 Dec 2020 17:19:14
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:33:37
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'updated' (Site from Safety).	Nick Bart (b) (4)	10 Nov 2020 15:46:44
DataPoint Un-verified.	Nick Bart (b) (4)	10 Nov 2020 15:46:38
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 15:46:38
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:26:55

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:08:21
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:49:33
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'downgraded from SAE to AE' (Site from Safety).	Nick Bart (b) (4)	16 Oct 2020 20:51:28
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 16:16:06
User entered 'Dose Delayed (DOSE DELAYED)'	Atanas Filev (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #8 recorded that matches this AE. However, the ConMed recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Feb 2021 10:18:14
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:43:51
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #8 recorded that matches this AE. However, the ConMed recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'eCRF updated. Dates reconciled. ' (Site from DM).	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 19:10:10
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Feb 2021 19:09:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Feb 2021 19:09:18
DataPoint Un-verified.	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 19:09:18
User entered '0' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 19:09:18
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #8 recorded that matches this AE. However, the ConMed recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 08:11:40
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:31:45

PRODUCTION RELEASE (v12.003
EAB) (1725)

2497 of 4253

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Oct 2020 20:51:30
User entered '1' reason for change: Data Entry Error	Nick Bart (b) (4)	16 Oct 2020 20:51:30
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Oct 2020 20:50:34
User entered '0' reason for change: Data Entry Error	Nick Bart (b) (4)	16 Oct 2020 20:50:34
User entered '1'	Atanas Filev (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:43:54
User entered '1' reason for change: Data Entry Error	Atanas Filev (b) (4)	10 Feb 2021 19:09:26
User entered '0'	(b) (4) Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:44:04
User entered '0'	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:31:51
User closed query 'PER CDM: RE-QUERY: Per previous query response 'Clarify preferred choice please for update. As the event is ongoing, outcome can be either Recovering/Resolving, Not Recovered/Not resolved (for example). Please update the outcome as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:53:06
Query 'PER CDM: RE-QUERY: Per previous query response 'Clarify preferred choice please for update. As the event is ongoing, outcome can be either Recovering/Resolving, Not Recovered/Not resolved (for example). Please update the outcome as appropriate. Thank you. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 15:45:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 15:44:53
User opened query 'PER CDM: RE-QUERY: Per previous query response 'Clarify preferred choice please for update. As the event is ongoing, outcome can be either Recovering/Resolving, Not Recovered/Not resolved (for example). Please update the outcome as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:09:09
User closed query 'PER CDM: AE Ongoing is YES, however outcome was recorded as unknown. Per CCG V2.0 Page 36, "Select 'Unknown' if it is not known whether the adverse event was resolved. This should only be used when the participant is lost to follow-up, and no other information can be obtained from that patient". Kindly consider updating the outcome as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:09:09

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Outcome](#)

Audit	User	Time (GMT)
Query 'PER CDM: AE Ongoing is YES, however outcome was recorded as unknown. Per CCG V2.0 Page 36, "Select 'Unknown' if it is not known whether the adverse event was resolved. This should only be used when the participant is lost to follow-up, and no other information can be obtained from that patient". Kindly consider updating the outcome as appropriate. Thank you.' answered with 'Clarify preferred choice please for update.' (Site from DM).	Nick Bart (b) (4)	22 Oct 2020 21:09:32
User opened query 'PER CDM: AE Ongoing is YES, however outcome was recorded as unknown. Per CCG V2.0 Page 36, "Select 'Unknown' if it is not known whether the adverse event was resolved. This should only be used when the participant is lost to follow-up, and no other information can be obtained from that patient". Kindly consider updating the outcome as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:56:18
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:49:37
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'downgraded from SAE to AE' (Site from Safety).	Nick Bart (b) (4)	16 Oct 2020 20:50:55
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 16:12:57
User entered 'Unknown (UNKNOWN)'	Atanas Filev (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Nov 2020 02:31:55
User entered empty.	Atanas Filev (b) (4) (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:24:34
User closed query 'Per DM CLR: Per SAE Narrative "NO TREATMENT PROVIDED". However, there is a conmed recorded that is given for this AE. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 11:39:57
Query 'Per DM CLR: Per SAE Narrative "NO TREATMENT PROVIDED". However, there is a conmed recorded that is given for this AE. Update as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:17:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:16:45
User entered 'PER SUBJECT REPORT AT SCREENING SUBJECT REPORTS LIVING IN AN APARTMENT WITH TWO ESSENTIAL WORKERS, AND HAS NOT CHANGED LIFESTYLE AND IS NOT SHELTERING IN PLACE.' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Apr 2021 16:16:45
User opened query 'Per DM CLR: Per SAE Narrative "NO TREATMENT PROVIDED". However, there is a conmed recorded that is given for this AE. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 07:52:13
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:45:34
User closed query 'PV Query: Please clarify whether the subject had an occupational risk, a location and living/circumstances risk, or an opportunity of exposure to SARS-COV-2.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 19:17:05
User closed query 'PV Query: Please provide additional information regarding the course of the event, including response to treatment and diagnostic test results at event resolution, if available.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 19:17:03

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please clarify whether the subject had an occupational risk, a location and living/circumstances risk, or an opportunity of exposure to SARS-COV-2.' answered with 'narrative updated' (Site from Safety).	Nick Bart (b) (4)	02 Dec 2020 16:59:36
Query 'PV Query: Please provide additional information regarding the course of the event, including response to treatment and diagnostic test results at event resolution, if available.' answered with 'No additional information to provide.' (Site from Safety).	Nick Bart (b) (4)	02 Dec 2020 16:59:31
User entered 'NO TREATMENT PROVIDED. Per subject report at Screening subject reports living in an apartment with two essential workers, and has not changed lifestyle and is not sheltering in place.' reason for change: Per Query Resolution	Nick Bart (b) (4)	02 Dec 2020 16:59:21
User opened query 'PV Query: Please clarify whether the subject had an occupational risk, a location and living/circumstances risk, or an opportunity of exposure to SARS-COV-2.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 23:46:51
User opened query 'PV Query: Please provide additional information regarding the course of the event, including response to treatment and diagnostic test results at event resolution, if available.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 23:45:52
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 02:32:01
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 02:31:58
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)	11 Nov 2020 15:33:21

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide additional information regarding the course of the event, including response to treatment and diagnostic test results at event resolution, if available.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:33:01
Query 'PV Query: Please provide additional information regarding the course of the event, including response to treatment and diagnostic test results at event resolution, if available.' answered with 'Medical records pending, will update' (Site from Safety).	Nick Bart (b) (4)	10 Nov 2020 19:38:16
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Resolution to this query, see updated narrative.' (Site from Safety).	Nick Bart (b) (4)	10 Nov 2020 19:38:08
User entered 'No treatment provided.' reason for change: Per Query Resolution	Nick Bart (b) (4)	10 Nov 2020 19:37:48
User opened query 'PV Query: Please provide additional information regarding the course of the event, including response to treatment and diagnostic test results at event resolution, if available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:08:12
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)	23 Oct 2020 20:07:28
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:49:43

PRODUCTION RELEASE (v12.003
EAB) (1725)

2506 of 4253

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:49:40
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'downgraded from SAE to AE' (Site from Safety).	Nick Bart (b) (4)	16 Oct 2020 20:50:53
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' answered with 'downgraded from SAE to AE' (Site from Safety).	Nick Bart (b) (4)	16 Oct 2020 20:50:50
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	16 Oct 2020 20:50:34
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 16:19:50
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 16:15:42
User entered 'Subject admitted to hospital 09 Oct 2020, secondary to COVID-19 infection. Had positive test done at ER on 06 Oct 2020. Experiencing T-max 103.1F, 02 Sat. at 93% with shortness of breath. Will update SAE once medical records are obtained.'	Atanas Filev (b) (4)	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '0'	System	16 Oct 2020 20:50:34
User entered '1'	System	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '0'	System	09 Oct 2020 20:16:48

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:03:15
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:03:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:03:03
User entered 'USA-US215-2020-mRNA-1273-P301000004'	System	05 Nov 2020 17:02:57
User entered 'New'	(b) (4), (b) (6)	05 Nov 2020 17:02:57

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:15
User coded data point as SOC: Cardiac disorders, HLGT: Pericardial disorders, HLT: Noninfectious pericarditis, PT: Pericarditis, LLT: Pericarditis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:11:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:11:50
Data point term sent to Coder	System	04 Nov 2020 22:11:11
User entered 'Pericarditis'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:17
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:19
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:21
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:23
User entered '31 Oct 2020'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:25
User entered empty.	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:27
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:28
User entered '03 Nov 2020'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:30
User entered empty.	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:35
User entered 'Grade 3/Severe (Grade 3/Severe)'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:33
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:37
User entered '0'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:39
User entered '0'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:41
User entered '1'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:43
User entered '31 Oct 2020'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:43:46
User entered '03 Nov 2020'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:41:26
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 22:43:55
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:43:48
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:41:28
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 22:43:57
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:43:53
User entered empty.	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:41:23
User entered '0'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:41:21
User entered '0'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:41:19
User entered '0'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:44:06
User entered 'Not Related (NOT RELATED)'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:44:30
User entered 'Not Related (NOT RELATED)'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User closed query 'PV Query: Please provide reason for action taken with study drug of not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 02:15:46
Query 'PV Query: Please provide reason for action taken with study drug of not applicable.' answered with 'N/A - IP withdrawn earlier in study, so now NA' (Site from Safety).	Mimi Van Der Leden	19 Nov 2020 21:53:06
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:44:42
User opened query 'PV Query: Please provide reason for action taken with study drug of not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:44:45
User entered '0'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:41:34
User entered '1'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:44:50
User entered '0'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:44:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:44:52
User entered empty.	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:18:49
User closed query 'Please add results of Echo, MRI, and EKG from this visit.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:18:47
Query 'Please add results of Echo, MRI, and EKG from this visit.' answered with 'Have all been added.' (Site from CRA).	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 19:10:38
User opened query 'Please add results of Echo, MRI, and EKG from this visit.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:24:16
User closed query 'Per DM CLR: SAE Narrative = SUBJECT HAD NEGATIVE CARDIAC WORK UP, INCLUDING NUCLEAR STRESS TEST. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 09:56:46
User closed query 'Per DM CLR: SAE Narrative = DIAGNOSED WITH A SMALL TO MEDIUM SIZED LOCULATED PERICARDIAL EFFUSION, NOTED ON CT. However, CT is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 09:56:40
Query 'Per DM CLR: SAE Narrative = DIAGNOSED WITH A SMALL TO MEDIUM SIZED LOCULATED PERICARDIAL EFFUSION, NOTED ON CT. However, CT is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'CT recorder accordingly.' (Site from DM).	Atanas Filev (b) (4) (b) (4)	30 Dec 2020 14:26:00
Query 'Per DM CLR: SAE Narrative = SUBJECT HAD NEGATIVE CARDIAC WORK UP, INCLUDING NUCLEAR STRESS TEST. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'Nuclear Stress Test recorded accordingly.' (Site from DM).	Atanas Filev (b) (4) (b) (4)	30 Dec 2020 14:25:50

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = SUBJECT HAD NEGATIVE CARDIAC WORK UP, INCLUDING NUCLEAR STRESS TEST. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 05:22:37
User opened query 'Per DM CLR: SAE Narrative = DIAGNOSED WITH A SMALL TO MEDIUM SIZED LOCULATED PERICARDIAL EFFUSION, NOTED ON CT. However, CT is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 05:22:30
User closed query 'PV Query: Please provide reason or cause of the event of pericarditis.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 02:15:56
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).	(b) (4), (b) (6)	21 Nov 2020 02:15:54

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT EXPERIENCED CHEST PAIN AND DIFFICULTY BREATHING ON 31 OCT 2020. WENT TO ED AND WAS ADMITTED WITH A DIAGNOSIS OF PERICARDITIS. SHE HAD AN UNCOMPLICATED COURSE AND WAS DISCHARGED ON 03 NOV 2020. PATIENT WAS ADMINISTERED 90 DAY COURSE OF COLCHICINE. FURTHER INFORMATION CAN BE PROVIDED ONCE MEDICAL RECORDS ARE OBTAINED. PER MEDICAL RECORD REVIEW, SUBJECT EXPERIENCED CHEST PAIN 31OCT2020. WAS ADMITTED TO HOSPITAL AND DIAGNOSED WITH A SMALL TO MEDIUM SIZED LOCULATED PERICARDIAL EFFUSION, NOTED ON CT. SUBJECT WAS STARTED ON FONDAPARINUX, ANTICOAGULANT SUBJECT HAD NEGATIVE CARDIAC WORK UP, INCLUDING NUCLEAR STRESS TEST. SUBJECT WAS STARTED ON A THREE MONTH COURSE OF COLCHICINE FOR POSSIBLE PERICARDITIS, PER CARDIOLOGY CONSULT. SUBJECT WAS DISCHARGED ON 03NOV2020. HAS SINCE BEEN SEEN AT SITE FEELING WELL AND ASYMPTOMATIC.' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 22:09:24
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 '01NOV2020 - covid + (remnant from earlier covid infection)' (Site from Safety).	Mimi Van Der Leden (b) (4)	19 Nov 2020 22:06:19

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT EXPERIENCED CHEST PAIN AND DIFFICULTY BREATHING ON 31 OCT 2020. WENT TO ED AND WAS ADMITTED WITH A DIAGNOSIS OF PERICARDITIS. SHE HAD AN UNCOMPLICATED COURSE AND WAS DISCHARGED ON 03 NOV 2020. PATIENT WAS ADMINISTERED 90 DAY COURSE OF COLCHICINE. FURTHER INFORMATION CAN BE PROVIDED ONCE MEDICAL RECORDS ARE OBTAINED. Per medical record review, subject experienced chest pain 31OCT2020. Was admitted to hospital and diagnosed with a small to medium sized loculated pericardial effusion, noted on CT. Subject was started on fondaparinux, anticoagulant and d/c when learned of no evidence of PE as cause for chest pain. Subject had negative cardiac work up, including nuclear stress test. Subject was started on a three month course of colchicine for possible pericarditis, per cardiology consult. Subject was discharged on 03NOV2020. Has since been seen at site feeling well and asymptomatic.' reason for change: New Information Query 'PV Query: Please provide reason or cause of the event of pericarditis.' answered with 'unknown etiology' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:05:54
User opened query 'PV Query: Please provide reason or cause of the event of pericarditis.' (Site from Safety).	Mimi Van Der Leden (b) (4)	19 Nov 2020 21:53:33
User opened query 'PV Query: Please provide reason or cause of the event of pericarditis.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:05:13
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)	13 Nov 2020 16:02:22
User entered 'Patient experienced chest pain and difficulty breathing on 31 Oct 2020. Went to ED and was admitted with a diagnosis of pericarditis. She had an uncomplicated course and was discharged on 03 Nov 2020. Patient was administered 90 day course of colchicine. Further information can be provided once medical records are obtained.'	Atanas Filev (b) (4) (b) (4)	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '0'	System	04 Nov 2020 22:10:37

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:18:30
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:18:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:18:31
Data point term sent to Coder	System	31 Mar 2021 18:17:48
User entered 'Elevated Blood Pressure'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:22:11
User closed query 'Please enter yes, as subject was present at the site when Elevated Blood Pressure noted.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:22:04
Query 'Please enter yes, as subject was present at the site when Elevated Blood Pressure noted.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:18:35
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 16:18:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 16:18:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:18:26
User opened query 'Please enter yes, as subject was present at the site when Elevated Blood Pressure noted.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 22:22:23
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 18:17:13
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:18:33
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 18:18:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 18:18:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 18:18:14
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 18:17:13
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:19:16
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:19:24
User entered '14 Jan 2021'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:22:10
User closed query 'PER CDM: RE-QUERY: Per CCG V5.0 page 49, Please note this field is not required, unless start time is within 24 hours of dosing time, then the field must be completed. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:56:32
Query 'PER CDM: RE-QUERY: Per CCG V5.0 page 49, Please note this field is not required, unless start time is within 24 hours of dosing time, then the field must be completed. Please review and update as appropriate. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:18:40
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:18:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:18:26
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:19:31
User opened query 'PER CDM: RE-QUERY: Per CCG V5.0 page 49, Please note this field is not required, unless start time is within 24 hours of dosing time, then the field must be completed. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 15:11:08
Query 'PER CDM: RE-QUERY: Per CCG V5.0 page 49, start time should be recorded only if the event start time is within 24 hours of dosing time. Please review and update if appropriate. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 15:11:04
User opened query 'PER CDM: RE-QUERY: Per CCG V5.0 page 49, start time should be recorded only if the event start time is within 24 hours of dosing time. Please review and update if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 15:09:41

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 15:09:36
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'start time relevant to AE' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 18:18:07
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Mar 2021 18:17:13
User entered '17:34'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	09 Apr 2021 16:18:26
User entered '14 Jan 2021 17:34'	System	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User closed query 'Per CDM: Please verify If AE #6 "Elevated Blood Pressure" has start date = 14JAN2021 and is marked as "Ongoing" = Yes, kindly confirm if the AE is still ongoing.Thanks	(b) (4) (b) (4), (b) (6)	13 Apr 2021 08:38:26
' (Site from DM). Query 'Per CDM: Please verify If AE #6 "Elevated Blood Pressure" has start date = 14JAN2021 and is marked as "Ongoing" = Yes, kindly confirm if the AE is still ongoing.Thanks	Atanas Filev (b) (4) (b) (4)	12 Apr 2021 21:26:34
' answered with 'AE was ongoing at the end of this patient's participation at the trial. ' (Site from DM). User opened query 'Per CDM: Please verify If AE #6 "Elevated Blood Pressure" has start date = 14JAN2021 and is marked as "Ongoing" = Yes, kindly confirm if the AE is still ongoing.Thanks	(b) (4), (b) (6)	10 Apr 2021 03:57:46
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:19:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:19:42
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:19:50
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:19:52
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:19:55
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:19:57
User entered '0'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:00
User entered '0'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:02
User entered '0'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:04
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:06
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:07
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:09
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:10
User entered '0'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:11
User entered '0'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:13
User entered '0'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:14
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:17
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:19
User entered '1'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:22
User entered '0'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:23
User entered '0'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:25
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:20:27
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '0'	System	31 Mar 2021 18:17:13

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '1'	System	09 Apr 2021 16:18:26

US3952033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:57:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:57:37
Data point term sent to Coder	System	09 Apr 2021 16:54:29
User entered 'LYMPHADENOPATHY'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered '09 Sep 2020'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered '16 Sep 2020'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered empty.	System	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered 'Related (RELATED)'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered 'None (NONE)'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered '1'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:26:17
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '0'	System	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '0'	System	09 Apr 2021 16:53:33

US3952033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:33:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:33:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User closed query 'Please add the ConMeds from the SAE of Gastritis when you have a moment.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:20:16
Query 'Please add the ConMeds from the SAE of Gastritis when you have a moment.' answered with 'Updated.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 14:21:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:13:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 20:30:46
User opened query 'Please add the ConMeds from the SAE of Gastritis when you have a moment.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 20:30:45
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:28:48
User closed query 'Per DM CLR: Per Diary Dose 1 Day 9, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:29:56
Query 'Per DM CLR: Per Diary Dose 1 Day 9, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'CM updated' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 19:56:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:33:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 9, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Nick Bart (b) (4)	06 Nov 2020 10:01:37 16 Sep 2020 16:34:57

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:29:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: PAROXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PAXIL [PAROXETINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 16:37:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 16:37:43
Data point term sent to Coder	System	16 Sep 2020 16:36:21
User entered 'paxil'	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:29:05
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:29:07
User entered 'depression'	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:29:09
User entered '40'	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:29:41
User entered 'mg (mg)'	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:29:43
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:29:45
User entered 'once daily (QD)'	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:29:47
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:29:48
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:29:51
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:29:56
User entered 'un UNK 1996'	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:29:58
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:23:10
User closed query 'Per MAR, Paroxetine discontinued 3Oct20.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:12:53
Query 'Per MAR, Paroxetine discontinued 3Oct20.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 22:52:53
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 22:52:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 22:52:38
User opened query 'Per MAR, Paroxetine discontinued 3Oct20.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:06:28
Query 'Per MAR, discontinued on 30Sep20.' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:05:16
User opened query 'Per MAR, discontinued on 30Sep20.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:54:15
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 20:53:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:30:00
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:22:56
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 22:52:38
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 22:52:38
User entered '03 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 22:52:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:30:02
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:30:04
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User entered '1'	System	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User entered '1'	System	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:37
User entered '804 (804)'	System	16 Sep 2020 16:35:38

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:47:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: OTHER ANTITHROMBOTIC AGENTS, PRODUCT: FONDAPARINUX SODIUM, PRODUCTSYNONYM: ARIXTRA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 16:38:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 16:38:40
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 16:37:23
User entered 'Arixtra'	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:47:20
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:30:13
Query 'Per ConMed list, 19Nov20, this is discrepant. Please confirm and update if needed.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:55:33
User opened query 'Per ConMed list, 19Nov20, this is discrepant. Please confirm and update if needed.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:54:23
User entered 'Antiphospholipid Syndrome'	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:54:25
User entered '10'	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:54:26
User entered 'mg (mg)'	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:54:28
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:54:29
User entered 'once daily (QD)'	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:54:31
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:54:33
User entered 'Subcutaneous (SUBCUTANEOUS)'	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:54:35
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:13:05
Query 'Per ConMed list, 19Nov20, this is discrepant. Please confirm and update if needed.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:55:30
User opened query 'Per ConMed list, 19Nov20, this is discrepant. Please confirm and update if needed.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:55:00
User entered 'un UNK 2011'	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:55:01
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:13:10
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:13:16
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:13:14
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 16:36:29

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 16:31:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 16:38:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 16:38:41
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 16:37:23
User entered 'Norco'	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:31:08
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 16:31:12
User entered 'chronic pain syndrome'	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 16:31:15
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:54:22
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 19:44:16
User entered '10/325' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 19:44:13
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:51:32
User entered '2'	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:31:21
User entered 'mg (mg)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 19:44:13
User entered 'tablet (TABLET)'	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:31:23
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 16:31:25
User entered 'twice daily (BID)'	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:31:27
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:31:29
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:31:31
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:31:37
User entered 'un UNK 2014'	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:31:38
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 16:31:40
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:31:42
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:31:44
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 16:37:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 16:31:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Sep 2020 13:30:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Sep 2020 13:30:47
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 16:38:27
User entered 'oxycodone'	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:31:54
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 16:31:56
User entered 'chronic pain syndrome'	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:32:00
User entered '10'	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:32:02
User entered 'mg (mg)'	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:32:04
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:32:06
User entered 'as needed (PRN)'	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:32:08
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:32:10
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:32:12
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:32:15
User entered 'un UNK 2014'	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:32:16
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 16:32:18
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:32:20
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:32:22
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 16:37:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:32:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 16:02:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 16:02:37
Data point term sent to Coder	System	10 Nov 2020 16:02:00
Coding entries removed.	Nick Bart (b) (4)	10 Nov 2020 16:01:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 16:40:37
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 Sep 2020 16:40:37
Data point term sent to Coder	System	16 Sep 2020 16:39:29
User entered 'acyclovir'	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:32:36
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:32:38
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of HERPES SIMPLEX. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:59:19
Query 'Per DM CLR: Please update the indication to reflect the location and type of HERPES SIMPLEX. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'herpes simplex i is of the oral area' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 16:01:19
User entered 'HERPES SIMPLEX i' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 16:01:14
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of HERPES SIMPLEX. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:51:58
User entered 'Herpes simplex'	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:32:40
User entered '200'	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:32:42
User entered 'mg (mg)'	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:32:44
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:32:46
User entered 'once daily (QD)'	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:32:49
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:32:50
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:32:52
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:32:56
User entered '08 Sep 2020'	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:32:59
User entered '0'	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:33:01
User entered 'No (N)' reason for change: New Information	Nick Bart (b) (4)	02 Oct 2020 14:14:45
User entered 'Yes (Y)'	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:33:05
User entered '14 Sep 2020' reason for change: New Information	Nick Bart (b) (4)	02 Oct 2020 14:14:45
User entered empty.	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:33:08
User entered 'No (N)'	Nick Bart (b) (4)	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User entered '1'	System	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User entered '1'	System	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:43
User entered '804 (804)'	System	16 Sep 2020 16:38:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
User closed query 'Still not present, please confirm source.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:35:34
Query 'Still not present, please confirm source.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:18:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User opened query 'Still not present, please confirm source.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:40:57
User closed query 'Not present, please add.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:40:57
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) (b) (4)	12 Apr 2021 05:56:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 05:56:45
User signature succeeded.	Mimi Van Der Leden (b) (4)	09 Apr 2021 20:15:23
Data point term sent to Coder	System	09 Apr 2021 15:35:33
Coding entries removed.	(b) (4), (b) (6)	09 Apr 2021 15:34:46
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) (b) (4)	03 Mar 2021 13:46:57
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 Mar 2021 13:46:57
Data point term sent to Coder	System	02 Mar 2021 16:40:36
Query 'Not present, please add.' answered with 'data updated' (Site from CRA).	Nick Bart (b) (4)	02 Mar 2021 16:40:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Nick Bart (b) (4)	02 Mar 2021 16:40:18
User opened query 'Not present, please add.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:59:52
User closed query 'ConMed Tylenol for Tenderness is not present on ConMed list. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:59:52
Query 'ConMed Tylenol for Tenderness is not present on ConMed list. Please reconcile and update if needed.' answered with 'present' (Site from CRA).	Nick Bart (b) (4)	28 Jan 2021 18:08:25
User opened query 'ConMed Tylenol for Tenderness is not present on ConMed list. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 16:36:08
Query 'This ConMed is missing from source.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 16:35:42
User opened query 'This ConMed is missing from source.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 16:35:36
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)	22 Nov 2020 05:49:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 05:49:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 04:57:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 04:57:45
Data point term sent to Coder	System	10 Nov 2020 19:48:38
User entered 'tylenol [acetaminophen]'	Nick Bart (b) (4)	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'No (N)'	Nick Bart	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MYALGIA is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MYALGIA did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 11:40:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MYALGIA is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MYALGIA did not meet the AE reporting criteria. ' answered with 'UPDATED' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:34:51
User entered 'COVID 19' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:34:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MYALGIA is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MYALGIA did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 09:56:07
User entered 'myalgia' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Mar 2021 16:40:18
User entered 'tenderness'	Nick Bart (b) (4)	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered '500'	Nick Bart	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'mg (mg)'	Nick Bart	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered empty.	Nick Bart	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'twice daily (BID)'	Nick Bart	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered empty.	Nick Bart	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'Oral (ORAL)'	Nick Bart	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered empty.	Nick Bart	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered '06 Sep 2020' reason for change: Per Query Resolution	(b) (4)	09 Apr 2021 15:33:26
User entered '05 Sep 2020' reason for change: Per Query Resolution	Nick Bart (b) (4)	02 Mar 2021 16:38:47
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	10 Nov 2020 19:50:08
User entered '02 Sep 2020' reason for change: Per Query Resolution	Nick Bart (b) (4)	10 Nov 2020 19:50:08
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	10 Nov 2020 19:48:26
User entered empty.	Nick Bart (b) (4)	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered '0'	Nick Bart	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Nov 2020 19:50:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 19:50:08
User entered 'No (N)' reason for change: Per Query Resolution	Nick Bart (b) (4)	10 Nov 2020 19:50:08
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:48:26
User entered empty.	Nick Bart (b) (4)	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered '12 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
User entered '15 Sep 2020' reason for change: Per Query Resolution	Nick Bart (b) (4)	02 Mar 2021 16:40:18
User entered empty.	Nick Bart (b) (4)	10 Nov 2020 19:50:08
		10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Nov 2020 19:50:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 19:50:08
User entered 'Yes (Y)' reason for change: Per Query Resolution	Nick Bart (b) (4)	10 Nov 2020 19:50:08
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:48:26
User entered empty.	Nick Bart (b) (4)	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
User entered '2'	System	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
User entered '1'	System	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:47
User entered '804 (804)'	System	10 Nov 2020 19:48:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:40:07
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)	10 Nov 2020 23:38:43
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 Nov 2020 23:38:43
Data point term sent to Coder	System	10 Nov 2020 20:50:37
User entered 'colchicine'	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:22
User entered 'No (N)'	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:24
User entered 'pericarditis'	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:26
User entered '0.6'	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:28
User entered 'mg (mg)'	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:30
User entered empty.	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:32
User entered 'once daily (QD)'	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:34
User entered empty.	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:35
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:37
User entered empty.	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:40:42
User closed query 'Per ETRTR, Please confirm start date and update if needed. According to AE, Hospital Admission Date is 30 Oct 2020' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 17:45:31
Query 'Per ETRTR, Please confirm start date and update if needed. According to AE, Hospital Admission Date is 30 Oct 2020' answered with 'Correct as entered. Subject experienced AE, went to hospital, and then was treated with medication.' (Site from CRA).	Nick Bart (b) (4)	20 Nov 2020 19:59:06
User opened query 'Per ETRTR, Please confirm start date and update if needed. According to AE, Hospital Admission Date is 30 Oct 2020' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:20:25
User entered '02 Nov 2020'	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:45
User entered '0'	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:46
User entered 'Yes (Y)'	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:49
User entered empty.	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:40:51
User entered 'No (N)'	Nick Bart (b) (4)	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 20:49:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:38:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:05
Data point term sent to Coder	System	20 Nov 2020 20:03:06
User entered 'tylenol extra strength [acetaminophen]'	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:38:05
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User closed query 'Per DM CLR: This Conmed is given for the AE#3. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Feb 2021 10:16:37
Query 'Per DM CLR: This Conmed is given for the AE#3. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'Source updated to reflect correct start date of medication. ' (Site from DM).	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 19:08:29
User opened query 'Per DM CLR: This Conmed is given for the AE#3. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:59:23
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:38:08
User entered 'covid-19 positive'	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:38:10
User entered '500'	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:38:11
User entered 'mg (mg)'	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:38:13
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:38:15
User entered 'three times daily (TID)'	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:38:17
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:40:19
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:40:21
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:00:47
DataPoint Un-verified.	Atanas Filev (b) (4)	10 Feb 2021 19:08:08
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	10 Feb 2021 19:08:08
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:40:23
User entered '03 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:40:25
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:40:27
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:40:29
User entered '13 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:40:31
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User entered '3'	System	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User entered '1'	System	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:22
User entered '804 (804)'	System	20 Nov 2020 20:02:46

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:19:55
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 Apr 2021 16:19:55
User signature succeeded.	Mimi Van Der Leden (b) (4)	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:42:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:04
Data point term sent to Coder	System	20 Nov 2020 20:09:17
User entered 'sodium chloride 0.9%'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:42:42
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:42:44
User entered 'pericarditis'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:42:46
User entered '200'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:42:47
User entered 'Other (OTHER)'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:42:49
User entered 'ml/hr'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:42:51
User entered 'other (OTHER)'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:42:52
User entered 'continuous'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:42:54
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:42:56
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 17:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 17:41:53
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:42:57
User entered '31 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:42:59
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:01
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:03
User entered '01 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:05
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User entered empty.	System	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User entered empty.	System	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:32
User entered empty.	System	20 Nov 2020 20:08:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:19:56
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 Apr 2021 16:19:56
User signature succeeded.	Mimi Van Der Leden (b) (4)	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:43:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:04
Data point term sent to Coder	System	20 Nov 2020 20:10:19
User entered 'sodium chloride 0.9%'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:14
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:16
User entered 'pericarditis'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:18
User entered '50'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:20
User entered 'Other (OTHER)'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:22
User entered 'ml/hr'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:23
User entered 'other (OTHER)'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:25
User entered 'continuous'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:27
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:29
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:31
User entered '01 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:33
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:35
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:37
User entered '02 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:43:39
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User entered empty.	System	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User entered empty.	System	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:56
User entered empty.	System	20 Nov 2020 20:09:34

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:44:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:13:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:13:02
Data point term sent to Coder	System	20 Nov 2020 20:12:20
User entered 'zofran'	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:44:41
User closed query 'Per DM CLR: Please confirm if this is used as prophylaxis. If not, please review and update response if this should be changed. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 07:13:03
Query 'Per DM CLR: Please confirm if this is used as prophylaxis. If not, please review and update response if this should be changed. Update eCRF as appropriate.' answered with 'Correct as entered. ' (Site from DM).	Nick Bart (b) (4)	21 Dec 2020 19:57:13
User opened query 'Per DM CLR: Please confirm if this is used as prophylaxis. If not, please review and update response if this should be changed. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:48:49
User entered 'Yes (Y)'	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:44:46
User closed query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 07:13:05
Query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification.' answered with 'Medication taken to prevent Nausea from occurring' (Site from DM).	Nick Bart (b) (4)	21 Dec 2020 19:57:25
User opened query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:48:32
User entered 'nausea'	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:44:48
User entered '4'	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:44:50
User entered 'mg (mg)'	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:44:52
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:44:54
User entered 'once (ONCE)'	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:44:57
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:44:59
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:01
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:03
User entered '31 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:05
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:15
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 16:45:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:45:07
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:13
User entered '31 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:17
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User entered empty.	System	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User entered empty.	System	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:02
User entered empty.	System	20 Nov 2020 20:11:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CHRONIC PAIN SYNDROME should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 11:09:25
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CHRONIC PAIN SYNDROME should be recorded, and update con med indication or provide clarification. ' answered with 'No AE needed. Not worsening' (Site from DM).	Nick Bart (b) (4)	02 Mar 2021 16:42:05
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CHRONIC PAIN SYNDROME should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 18:01:12
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:45:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:14:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:14:03
Data point term sent to Coder	System	20 Nov 2020 20:13:23
User entered 'oxycodone'	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:32
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:35
User entered 'chronic pain syndrome'	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:36
User entered '10'	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:38
User entered 'mg (mg)'	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:39
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:41
User entered 'once daily (QD)'	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:43
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:44
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:46
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:48
User entered '31 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:50
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:52
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:54
User entered '01 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:45:56
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User entered '1'	System	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User entered '1'	System	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:06
User entered '804 (804)'	System	20 Nov 2020 20:12:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:02
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: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:15:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:15:07
Data point term sent to Coder	System	20 Nov 2020 20:14:24
User entered 'protonix'	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:04
User closed query 'Per DM CLR: Please confirm if this is used as prophylaxis. If not, please review and update response if this should be changed. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 07:13:14
Query 'Per DM CLR: Please confirm if this is used as prophylaxis. If not, please review and update response if this should be changed. Update eCRF as appropriate.' answered with 'Correct as entered' (Site from DM).	Nick Bart (b) (4)	21 Dec 2020 19:58:14
User opened query 'Per DM CLR: Please confirm if this is used as prophylaxis. If not, please review and update response if this should be changed. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:50:03
User entered 'Yes (Y)'	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:06
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 07:13:16
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'taken as prophylactic against this indication' (Site from DM).	Nick Bart (b) (4)	21 Dec 2020 19:58:34
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:49:44
User entered 'gastroesophageal reflux disease'	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:08
User entered '40'	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:10
User entered 'mg (mg)'	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:12
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:36:03
User closed query 'Med records and ConMed log do not match. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:36:01
Query 'Med records and ConMed log do not match. Please reconcile.' answered with 'twice daily updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 22:55:42
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:46:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User opened query 'Med records and ConMed log do not match. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:43:41
User closed query 'Per Medical records, page 107 subject received 40 mg of Protonix from 02Nov20 twice daily. ConMed List page 6 states subject received Protonix once daily. Please confirm and update if needed.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:43:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
Query 'Per Medical records, page 107 subject received 40 mg of Protonix from 02Nov20 twice daily. ConMed List page 6 states subject received Protonix once daily. Please confirm and update if needed.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:47:49
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:47:37
User opened query 'Per Medical records, page 107 subject received 40 mg of Protonix from 02Nov20 twice daily. ConMed List page 6 states subject received Protonix once daily. Please confirm and update if needed.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 17:38:45
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 17:37:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:46:26
User entered 'once daily (QD)'	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:28
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:31
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:33
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:36
User entered '01 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:37
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:40
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:42
User entered '03 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:44
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User entered '2'	System	09 Apr 2021 15:47:37
User entered '1'	System	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User entered '1'	System	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:11
User entered '804 (804)'	System	20 Nov 2020 20:13:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:53
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: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 21:57:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 21:57:20
Data point term sent to Coder	System	02 Dec 2020 17:14:26
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	02 Dec 2020 17:14:08
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	Nick Bart (b) (4)	02 Dec 2020 17:14:08
User entered 'PROTONIX [pantoprazole sodium]' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:14:02

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 11:12:08
Data point term sent to Coder	System	20 Nov 2020 20:15:25
User entered 'protonix'	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:55
User closed query 'Per DM CLR: Please confirm if this is used as prophylaxis. If not, please review and update response if this should be changed. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 07:13:25
Query 'Per DM CLR: Please confirm if this is used as prophylaxis. If not, please review and update response if this should be changed. Update eCRF as appropriate.' answered with 'Correct as entered' (Site from DM).	Nick Bart (b) (4)	21 Dec 2020 19:58:50
User opened query 'Per DM CLR: Please confirm if this is used as prophylaxis. If not, please review and update response if this should be changed. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:50:38
User entered 'Yes (Y)'	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:46:57
User entered 'gastroesophageal reflux disease'	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:00
User entered '40'	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:18:15
User closed query 'Per DM CLR-RQ: Please provide dose in "MG" as the intravenous dose of this medication can be diluted in various amount of liquid in ML. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 06:50:16
Query 'Per DM CLR-RQ: Please provide dose in "MG" as the intravenous dose of this medication can be diluted in various amount of liquid in ML. Update as appropriate. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	28 Jan 2021 18:16:59
DataPoint Un-verified.	Nick Bart (b) (4)	28 Jan 2021 18:16:55
User entered 'mg (mg)' reason for change: Data Entry Error	Nick Bart (b) (4)	28 Jan 2021 18:16:55
User opened query 'Per DM CLR-RQ: Please provide dose in "MG" as the intravenous dose of this medication can be diluted in various amount of liquid in ML. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 18:04:12
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 17:37:02
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 17:34:45
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:47:02
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable or provide explanation on alternate dose. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 07:13:28

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable or provide explanation on alternate dose. ' answered with 'Subject received 40mL of Protonix as a liquid via IV route. Correct as entered' (Site from DM).	Nick Bart (b) (4)	21 Dec 2020 19:59:26
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable or provide explanation on alternate dose. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:50:53
User entered 'mL (mL)'	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:03
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:05
User entered 'once (ONCE)'	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:07
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:09
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:11
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:13
User entered '01 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:15
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:16
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:18
User entered '01 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:20
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User entered empty.	System	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User entered empty.	System	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:51
User entered empty.	System	20 Nov 2020 20:14:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:02
Data point term sent to Coder	System	20 Nov 2020 20:17:27
User entered 'potassium chloride'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:26
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:29
User entered 'pericarditis'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:31
User entered '40'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:32
User entered 'Other (OTHER)'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:35
User entered 'mEq/L'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:37
User entered 'other (OTHER)'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:39
User entered 'every four hours'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:42
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:44
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:45
User entered '02 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:47
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:49
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:51
User entered '02 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:47:53
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User entered empty.	System	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User entered empty.	System	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:19
User entered empty.	System	20 Nov 2020 20:17:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:48:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:20:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:20:02
Data point term sent to Coder	System	20 Nov 2020 20:19:30
User entered 'norco'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:48:02
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:48:04
User entered 'pericarditis'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:48:07
User entered '15/650'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:48:09
User entered 'mg (mg)'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:48:11
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:48:13
User entered 'other (OTHER)'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:48:15
User entered 'prn q4hours'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:48:18
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:48:20
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:50:09
User entered '01 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:50:11
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:50:13
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:50:14
User entered '03 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:50:16
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User entered empty.	System	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User entered empty.	System	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:47
User entered empty.	System	20 Nov 2020 20:19:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 11:09:55
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification.' answered with 'no AE needed. MH did not worsen' (Site from DM).	Nick Bart (b) (4)	02 Mar 2021 16:52:02
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 18:05:02
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:51:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:21:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:21:03
Data point term sent to Coder	System	20 Nov 2020 20:20:31
User entered 'ativan'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:28
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:30
User entered 'anxiety'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:32
User entered '2'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:34
User entered 'mg (mg)'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:36
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:38
User entered 'other (OTHER)'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:39
User entered 'prn q4hours'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:41
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:42
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:44
User entered '01 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:47
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:50
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:52
User entered '02 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:51:54
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User entered empty.	System	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User entered empty.	System	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:38
User entered empty.	System	20 Nov 2020 20:20:10

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 17:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 17:07:49
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:52:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:53
Data point term sent to Coder	System	20 Nov 2020 20:21:31
User entered 'morphine'	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:52:03
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:52:05
User entered 'pericarditis'	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:52:06
User entered '2'	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:52:08
User entered 'mg (mg)'	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:52:10
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:52:12
User entered 'once (ONCE)'	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:52:14
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:52:15
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:52:17
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:52:20
User entered '01 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:02
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User closed query 'Per ConMed List, page 5, no source present to confirm this. Please reconcile and update if needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:03:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 20:03:05
Query 'Per ConMed List, page 5, no source present to confirm this. Please reconcile and update if needed.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	28 Jan 2021 18:23:00
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4)	28 Jan 2021 18:22:48
Query 'Per Medical records, page 105, subject completed morphine IV on 01Nov20. But ConMed list page 5, information is not present. Please reconcile and update if needed.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 17:09:23
User opened query 'Per Medical records, page 105, subject completed morphine IV on 01Nov20. But ConMed list page 5, information is not present. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 17:09:21
User opened query 'Per ConMed List, page 5, no source present to confirm this. Please reconcile and update if needed.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 16:53:38
User entered 'Yes (Y)'	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:03:11
User entered '01 Nov 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	28 Jan 2021 18:22:48
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 17:08:28
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:05
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:07
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User entered empty.	System	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User entered empty.	System	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:42
User entered empty.	System	20 Nov 2020 20:20:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:53
Data point term sent to Coder	System	20 Nov 2020 20:25:34
User entered 'morphine'	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:49
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:52
User entered 'pericarditis'	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:54
User entered '4'	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:56
User entered 'mg (mg)'	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:58
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:01
User entered 'twice daily (BID)'	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:02
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:05
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:06
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:09
User entered '31 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:11
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:13
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:15
User entered '31 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:17
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User entered '2'	System	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User entered '1'	System	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:05
User entered '804 (804)'	System	20 Nov 2020 20:24:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:24
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) (b) (4)	21 Nov 2020 09:05:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:00
Data point term sent to Coder	System	20 Nov 2020 20:26:35
User entered 'nitroglycerin'	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:26
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:28
User entered 'pericarditis'	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:31
User entered '0.4'	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:33
User entered 'mg (mg)'	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:34
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:37
User entered 'once (ONCE)'	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:40
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:43
User entered 'Other (OTHER)'	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:45
User entered 'sublingual '	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:46
User entered '31 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:49
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:50
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:52
User entered '31 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:54:54
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User entered empty.	System	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User entered empty.	System	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:08
User entered empty.	System	20 Nov 2020 20:26:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:55:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: OTHER ANTITHROMBOTIC AGENTS, PRODUCT: FONDAPARINUX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:34
Data point term sent to Coder	System	20 Nov 2020 20:29:38
User entered 'Fondaparinux'	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:55:06
User closed query 'Per DM CLR: Please confirm if this is used as prophylaxis. If not, please review and update response if this should be changed. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 07:13:38
Query 'Per DM CLR: Please confirm if this is used as prophylaxis. If not, please review and update response if this should be changed. Update eCRF as appropriate.' answered with 'correct as entered' (Site from DM).	Nick Bart (b) (4)	21 Dec 2020 20:00:12
User opened query 'Per DM CLR: Please confirm if this is used as prophylaxis. If not, please review and update response if this should be changed. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:51:51
User entered 'Yes (Y)'	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:55:11
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 07:13:40
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Taken prophylactically against this indication' (Site from DM).	Nick Bart (b) (4)	21 Dec 2020 20:00:30
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:51:39
User entered 'deep vein thrombosis'	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:03:49
User closed query 'Per Medical records, page 103 subject received 10 mg of FondaPurinx on 03Nov20. ConMed List page 6 states subject received 0.8ml. Please confirm and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 20:03:47
Query 'Per Medical records, page 103 subject received 10 mg of FondaPurinx on 03Nov20. ConMed List page 6 states subject received 0.8ml. Please confirm and update if needed. ' answered with '0.8mL injection is correct per late correction 07Jan2021' (Site from CRA).	Nick Bart (b) (4)	28 Jan 2021 18:26:38
User opened query 'Per Medical records, page 103 subject received 10 mg of FondaPurinx on 03Nov20. ConMed List page 6 states subject received 0.8ml. Please confirm and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 17:03:09
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 17:02:10
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:55:14
User entered '0.8'	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:03:55
User closed query 'Per Medical records, page 103 subject received 10 mg of FondaPurinx on 03Nov20. ConMed List page 6 states subject received 0.8ml. Please confirm and update if needed.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 20:03:53
Query 'Per Medical records, page 103 subject received 10 mg of FondaPurinx on 03Nov20. ConMed List page 6 states subject received 0.8ml. Please confirm and update if needed.' answered with 'answered with '0.8mL injection is correct per late correction 07Jan2021' (Site from CRA).	Nick Bart (b) (4)	28 Jan 2021 18:26:58
User opened query 'Per Medical records, page 103 subject received 10 mg of FondaPurinx on 03Nov20. ConMed List page 6 states subject received 0.8ml. Please confirm and update if needed.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 17:03:28
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 17:03:19
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:55:16
User entered 'mL (mL)'	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:55:19
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:55:21
User entered 'once daily (QD)'	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:55:23
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:55:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:55:27
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
Query 'Per Medical records, page 103 subject received FondaPurinix on 03Nov20. Please confirm and update if needed.' canceled (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:04:49
	(b) (4), (b) (6)	10 Feb 2021 20:04:39
User opened query 'Per Medical records, page 103 subject received FondaPurinix on 03Nov20. Please confirm and update if needed.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 17:01:22
	(b) (4), (b) (6)	06 Jan 2021 17:00:26
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:57:20
User entered '31 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:57:22
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:57:24
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:57:26
User entered '31 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:57:33
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User entered '1'	System	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User entered '1'	System	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:32:14
User entered '804 (804)'	System	20 Nov 2020 20:28:44

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:27:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:31:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:31:08
Data point term sent to Coder	System	20 Nov 2020 20:30:45
User entered 'acetaminophen'	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:27:48
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:27:51
User entered 'pericarditis'	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:27:53
User entered '650'	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:27:55
User entered 'mg (mg)'	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:27:59
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:28:01
User entered 'once daily (QD)'	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:28:04
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:28:06
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:28:08
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:28:10
User entered '31 Oct 2020'	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:28:12
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:28:36
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:37:32
Query 'Per the EMAR (page 101) on 12Nov20, this is discrepant. Please confirm and update if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:37:30
User opened query 'Per the EMAR (page 101) on 12Nov20, this is discrepant. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:36:03
User entered '01 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:36:17
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User entered '1'	System	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User entered '1'	System	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:52
User entered '804 (804)'	System	20 Nov 2020 20:30:35

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM, PRODUCTSYNONYM: KLONOPIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:34:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:34:03
Data point term sent to Coder	System	20 Nov 2020 20:32:54
User entered 'klonopin'	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:34
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:51
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 21:38:35
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:38:31
User entered 'anxiety'	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:26
User entered '0.5'	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:23
User entered 'mg (mg)'	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:21
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:18
User entered 'once daily (QD)'	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:19
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:14
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:16
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:05
User entered '01 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:07
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:08
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:11
User entered '02 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:38:12
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User entered '1'	System	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User entered '1'	System	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:56
User entered '804 (804)'	System	20 Nov 2020 20:31:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:42:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:34:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:34:02
Data point term sent to Coder	System	20 Nov 2020 20:32:54
User entered 'fluoxetine'	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DEPRESSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 11:10:34
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DEPRESSION should be recorded, and update con med indication or provide clarification. ' answered with 'No AE needed, not worsening condition' (Site from DM).	Nick Bart (b) (4)	02 Mar 2021 16:52:44
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DEPRESSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 18:05:35
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:42:30
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:37:05
User closed query 'Not in source. Please update source.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:37:04
Query 'Not in source. Please update source.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:14:36
User opened query 'Not in source. Please update source.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:52:16
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:52:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:58:07
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 21:45:31
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:45:19
User entered 'depression'	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:45:21
User entered '20'	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:45:22
User entered 'mg (mg)'	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:45:24
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:45:27
User entered 'once daily (QD)'	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:45:29
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:45:33
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:45:34
User entered empty.	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:45:36
User entered '01 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:45:38
User entered '0'	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:45:40
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:45:42
User entered '03 Nov 2020'	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:46:01
User entered 'No (N)'	Nick Bart (b) (4)	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User entered '1'	System	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User entered '1'	System	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:31:59
User entered '804 (804)'	System	20 Nov 2020 20:32:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:23
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
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.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 15:55:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:55:39
Data point term sent to Coder	System	09 Apr 2021 15:51:12
User entered 'PREDNISONE'	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:36
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'RHEUMATOID ARTHRITIS'	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:38
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered '20'	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:47
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered empty.	(b) (4)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:49
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:50
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered empty.	(b) (4)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered '11 Jan 2021'	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:49:00
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered '17 Jan 2021'	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:49:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
User entered '1'	System	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
User entered '1'	System	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:57
User entered '804 (804)'	System	09 Apr 2021 15:50:26

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:51:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 15:55:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:55:50
Data point term sent to Coder	System	09 Apr 2021 15:52:14
User entered 'TYLENOL'	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:51:55
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:51:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'MYALGIA'	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:00
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered '650'	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:03
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:07
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'three times daily (TID)'	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:14
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:18
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered '05 Sep 2020'	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:20
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:21
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:23
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered '12 Sep 2020'	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
User entered '3'	System	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
User entered '1'	System	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:00
User entered '804 (804)'	System	09 Apr 2021 15:52:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: PAROXETINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:21:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:21:59
Data point term sent to Coder	System	13 Apr 2021 13:20:48
User entered 'PAROXETINE'	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	13 Apr 2021 17:52:37
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:39
User entered 'DEPRESSION'	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:41
User entered '10'	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:43
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:45
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	13 Apr 2021 17:52:47
	(b) (4), (b) (6)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:49
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:52
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:55
User entered '26 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	13 Apr 2021 17:52:57
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:01
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:02
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 13:19:59

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:53:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:23:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:23:56
	(b) (4)	
Data point term sent to Coder	System	13 Apr 2021 13:22:49
User entered 'FLUOXETINE'	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:53:13
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:15
User entered 'DEPRESSION'	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:53:18
User entered '20'	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:21
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:23
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:53:27
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:53:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:30
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:32
User entered '23 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:33
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:37
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	13 Apr 2021 17:53:39
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 13:21:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Apr 2021 13:21:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 13:21:53
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 13:21:49
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 13:21:49

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:53:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:23:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:23:56
	(b) (4)	
Data point term sent to Coder	System	13 Apr 2021 13:22:49
User entered 'CLONAZEPAM'	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:00
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:02
User entered 'ANXIETY'	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:03
User entered '0.5'	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:54:07
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:09
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:54:10
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:54:14
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:54:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:54:22
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:54:24
User entered '03 Nov 2020'	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:54:26
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:54:30
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:54:33
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 13:22:37

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:54:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:25:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:25:03
	(b) (4)	
Data point term sent to Coder	System	13 Apr 2021 13:23:50
User entered 'MELATONIN'	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:37:32
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 22:58:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 22:58:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:55
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:37:30
User closed query 'No AE present, please confirm if Melatonin is prophylaxis. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:37:25
Query 'No AE present, please confirm if Melatonin is prophylaxis. Please reconcile.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 22:58:59
User opened query 'No AE present, please confirm if Melatonin is prophylaxis. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:37:14
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:54
Query 'No AE present, please confirm if Melatonin is prophylaxis. Please reconcile.' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:36:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User opened query 'No AE present, please confirm if Melatonin is prophylaxis. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:08:37
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:55:00
User entered 'INSOMNIA'	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:55:03
User entered '3'	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:55:09
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:55:11
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	13 Apr 2021 17:55:13
	(b) (4), (b) (6)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:55:15
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:55:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:55:20
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:55:25
User entered '08 Jun 2020'	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:55:27
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:55:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:55:30
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:55:32
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 13:23:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:22:52
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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:25:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:25:55
	(b) (4)	
Data point term sent to Coder	System	13 Apr 2021 13:24:51
User entered 'PANTOPRAZOLE'	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:22:53
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:23:06
User entered 'GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:23:11
User entered '40'	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	13 Apr 2021 18:23:12
	(b) (4), (b) (6)	
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	13 Apr 2021 18:23:17
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:23:21
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:23:23
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:23:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:23:27
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:23:28
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:23:30
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:23:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:23:33
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:23:35
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 13:24:33

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:24:13
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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:27:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:27:02
	(b) (4)	
Data point term sent to Coder	System	13 Apr 2021 13:25:53
User entered 'PANTOPRAZOLE'	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:24:16
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:24:19
User entered 'GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:24:21
User entered '40'	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:24:25
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:24:27
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:24:29
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:24:30
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:24:32
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:24:34
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	13 Apr 2021 18:24:37
	(b) (4), (b) (6)	
User entered '20 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:24:38
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:24:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:24:42
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:24:43
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 13:25:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this meets EC#12, if so, please raise PD accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 07:28:32
Query 'Per MM, Please confirm if this meets EC#12, if so, please raise PD accordingly.' answered with 'Per MM on ePif # 427987 The use of immunosuppressants in the 6 months prior is not exclusionary to open label dosing. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 17:16:04
User opened query 'Per MM, Please confirm if this meets EC#12, if so, please raise PD accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 00:21:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:24:58
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: SELECTIVE IMMUNOSUPPRESSANTS, PRODUCT: ABATACEPT - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:31:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:31:53
Data point term sent to Coder	System	13 Apr 2021 13:26:57
User entered 'ABATACEPT'	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:24:59
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:25:01
User entered 'RHEUMATOID ARTHRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:25:04
User entered '125'	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:40:35
User closed query 'Per ConMed, mg/mL is unit.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:40:34
Query 'Per ConMed, mg/mL is unit.' answered with 'updated ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 22:59:43
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 22:59:36
User entered 'Other (OTHER)' reason for change:	(b) (4), (b) (6)	13 Apr 2021 22:59:36
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User opened query 'Per ConMed, mg/mL is unit.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:25:22
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	14 Apr 2021 16:40:37
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 22:59:36
User entered 'mg/mL' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 22:59:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:25:24
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:25:25
User entered 'every week (QS)'	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:25:30
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:25:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:25:34
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:25:37
User entered '10 Jun 2020'	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:25:40
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:25:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:25:44
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4)	13 Apr 2021 18:25:47
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	13 Apr 2021 13:26:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:29:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:29:08
Data point term sent to Coder	System	13 Apr 2021 13:28:00
User entered 'DOXYCYCLINE'	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:06
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:08
User entered 'COVID-19'	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:10
User entered '100'	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:14
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:16
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:18
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:21
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:24
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:26
User entered '06 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:28
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:29
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:31
User entered '05 Nov 2020'	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:33
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User entered '2'	System	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User entered '1'	System	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:10
User entered '804 (804)'	System	13 Apr 2021 13:27:00

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:29:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:29:55
Data point term sent to Coder	System	13 Apr 2021 13:29:03
User entered 'FLONASE'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:53
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:54
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:56
User entered '50'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:26:58
User entered 'Other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:00
User entered 'mcg'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:01
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:04
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:06
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:08
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:11
User entered '06 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:14
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:16
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:18
User entered '05 Nov 2020'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:20
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User entered '1'	System	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User entered '1'	System	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:13
User entered '804 (804)'	System	13 Apr 2021 13:28:07

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: LACTOBACILLUS ACIDOPHILUS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Apr 2021 08:50:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:50:48
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:27:25
Data point term sent to Coder	System	13 Apr 2021 13:31:04
User entered 'lactobacillus acidophilus'	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:30
User entered 'Prophylactic'	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:32
User entered '1'	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:34
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:37
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:38
User entered 'three times daily (TID)'	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:40
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:43
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:45
User entered '06 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:48
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:50
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:27:55
User entered '05 Nov 2020'	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:28:04
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User entered '3'	System	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User entered '1'	System	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:58
User entered '804 (804)'	System	13 Apr 2021 13:30:16

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, NON-IODINATED, ATC: BARIUM SULFATE CONTAINING X-RAY CONTRAST MEDIA, PRODUCT: BARIUM SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 07:48:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 07:48:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:28:18
Data point term sent to Coder	System	13 Apr 2021 13:32:09
User entered 'barium sulfate oral suspension 2%'	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:28:20
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:28:22
User entered 'Imaging (Barium Swallow)'	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:28:24
User entered '450'	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:28:27
User entered 'mL (mL)'	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:28:39
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:41:04
User closed query 'Subject received once but dates listed 5Aug20. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:41:02
Query 'Subject received once but dates listed 5Aug20. Please reconcile.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:26:34
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 16:26:24
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 16:26:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User opened query 'Subject received once but dates listed 5Aug20. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:29:31
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:29:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:28:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:29:34
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:29:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:29:37
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:29:42
User entered '05 Aug 2020'	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:29:44
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:29:45
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:29:47
User entered '03 Nov 2020'	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:29:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User entered empty.	System	14 Apr 2021 16:26:24
User entered '1'	System	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User entered empty.	System	14 Apr 2021 16:26:24
User entered '1'	System	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:01
User entered empty.	System	14 Apr 2021 16:26:24
User entered '804 (804)'	System	13 Apr 2021 13:31:45

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: MOXIFLOXACIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 13:18:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:18:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:30:03
Data point term sent to Coder	System	13 Apr 2021 13:33:10
User entered 'MOXIFLAXACIN'	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:05
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:06
User entered 'CELLULITIS'	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:08
User entered '400'	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:11
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:16
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:18
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:19
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:21
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:23
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:25
User entered '01 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:27
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:29
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:31
User entered '08 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:33
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User entered '1'	System	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User entered '1'	System	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:05
User entered '804 (804)'	System	13 Apr 2021 13:32:55

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 09:24:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 09:24:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:30:48
Data point term sent to Coder	System	13 Apr 2021 13:34:11
User entered 'COMPAZINE'	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:51
User entered 'GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:53
User entered '10'	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:55
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:57
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:30:59
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:02
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:06
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:10
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:11
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:13
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:15
User entered '30 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:18
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User entered '2'	System	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User entered '1'	System	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:17
User entered '804 (804)'	System	13 Apr 2021 13:33:40

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 08:14:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 08:14:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:31:32
Data point term sent to Coder	System	13 Apr 2021 13:35:12
User entered 'VANCOMYCIN'	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:34
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:36
User entered 'C DIFF'	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:40
User entered '125'	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:42
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:44
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:46
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:49
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:52
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:55
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:31:58
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:02
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:04
User entered '10 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:06
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User entered '2'	System	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User entered '1'	System	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:30
User entered '804 (804)'	System	13 Apr 2021 13:34:41

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:37:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:37:08
Data point term sent to Coder	System	13 Apr 2021 13:36:13
User entered 'ZOFRAN'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:20
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:21
User entered 'NAUSEA'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:24
User entered '4'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:25
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:27
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:29
User entered 'other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:31
User entered 'q12hrs'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:36
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:38
User entered '11 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:40
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:42
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:44
User entered '11 Oct 2020'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:32:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User entered empty.	System	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User entered empty.	System	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:34
User entered empty.	System	13 Apr 2021 13:35:48

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:02:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:38:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:38:00
Data point term sent to Coder	System	13 Apr 2021 13:37:14
User entered 'MELATONIN'	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:41:29
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:01:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:01:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:02:05
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User closed query 'Not present in Medical Hx or in AE. Melatonin often a supplement. Please confirm if received/given prophylactically.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:41:27
Query 'Not present in Medical Hx or in AE. Melatonin often a supplement. Please confirm if received/given prophylactically.' answered with 'Updated, yes supplement was given prophylactically' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:01:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User opened query 'Not present in Medical Hx or in AE. Melatonin often a supplement. Please confirm if received/given prophylactically.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:02:01
User entered 'INSOMNIA'	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:02:06
User entered '5'	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:02:08
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:02:11
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:02:12
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:02:14
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:02:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:02:18
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:03:32
User entered '26 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:03:35
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:03:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:03:39
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:03:41
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User entered '1'	System	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User entered '1'	System	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:39
User entered '804 (804)'	System	13 Apr 2021 13:36:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:37:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:39:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:39:01
Data point term sent to Coder	System	13 Apr 2021 13:38:14
User entered 'acetaminophen'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:37:40
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:37:42
User entered 'headache'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:37:44
User entered '500'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:37:46
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:37:55
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:30
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:57
User entered 'other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:10
User entered 'Q6HRS'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:11
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:13
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:16
User entered '26 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:20
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:23
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User entered empty.	System	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User entered empty.	System	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:42
User entered empty.	System	13 Apr 2021 13:37:24

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:40:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:40:10
Data point term sent to Coder	System	13 Apr 2021 13:39:15
User entered 'COMPAZINE'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:41
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:43
User entered 'NAUSEA'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:47
User entered '10'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:49
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:52
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:53
User entered 'other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:55
User entered 'q4hr'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:38:59
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:01
User entered '27 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:03
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:04
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:08
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User entered empty.	System	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User entered empty.	System	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:47
User entered empty.	System	13 Apr 2021 13:38:36

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:41:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:41:59
Data point term sent to Coder	System	13 Apr 2021 13:41:17
User entered 'pantoprazole'	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'gastritis'	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '40'	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User entered '1'	System	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User entered '1'	System	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:34
User entered '804 (804)'	System	13 Apr 2021 13:40:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: MOXIFLOXACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 13:18:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 13:18:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 13:42:18
User entered 'moxifloxacin'	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'cellulitis'	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '400'	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '29 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User entered '1'	System	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User entered '1'	System	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:29
User entered '804 (804)'	System	13 Apr 2021 13:41:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: OTHER ANTITHROMBOTIC AGENTS, PRODUCT: FONDAPARINUX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 10:38:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 10:38:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 13:43:19
User entered 'Fondaparinux'	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'PROPHYLAXIS DVT'	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:41:55
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:02:01
User entered '10/0.3' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '10'	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:41:57
User closed query 'Dose should be 10mg/0.3mL. Please update.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:41:53
Query 'Dose should be 10mg/0.3mL. Please update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:02:06
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:02:01
User opened query 'Dose should be 10mg/0.3mL. Please update.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:36:27
Query 'Dose unit should be 10mg/0.3mL.' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:36:12
User opened query 'Dose unit should be 10mg/0.3mL.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:40:41
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:40:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:41:58
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:02:01
User entered 'mg/mL' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '27 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User entered '1'	System	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User entered '1'	System	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:33:23
User entered '804 (804)'	System	13 Apr 2021 13:42:51

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: OXYMETAZOLINE, PRODUCTSYNONYM: AFRIN [OXYMETAZOLINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 07:16:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	14 Apr 2021 07:16:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 13:44:29
User entered 'AFRIN NASAL SPRAY 0.05%'	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '1'	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'puff (PUFF)'	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '29 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User entered '2'	System	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User entered '1'	System	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:27
User entered '804 (804)'	System	13 Apr 2021 13:43:47

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 12:52:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 12:52:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	13 Apr 2021 14:15:59 13 Apr 2021 14:15:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:46:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:46:08
Data point term sent to Coder User entered 'OXYCODONE'	System (b) (4), (b) (6)	13 Apr 2021 13:45:30 13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'PAIN secondary to gastritis' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 14:15:57
User entered 'PAIN'	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '10'	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'TID PRN'	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User entered empty.	System	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User entered empty.	System	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:22
User entered empty.	System	13 Apr 2021 13:44:30

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 08:53:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	14 Apr 2021 08:53:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 13:46:31
User entered 'SODIUM CHLORIDE 0.9%'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'PROPHYLAXIS FLUIDS'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:42:20
User closed query 'Should be 100/1000 mL/mg' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:42:18
Query 'Should be 100/1000 mL/mg' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:02:41
User entered '100/1000' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:02:35
User opened query 'Should be 100/1000 mL/mg' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:43:03
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:42:13
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '100'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:42:22
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:02:35
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:42:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mL (mL)'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:42:23
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:02:35
User entered 'mL/mg' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:02:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Continuous'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '26 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User entered empty.	System	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User entered empty.	System	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:38:25
User entered empty.	System	13 Apr 2021 13:46:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 08:03:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:03:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 13:47:32
User entered 'ZOFRAN'	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:42:32
User closed query 'Unclear, 3 or 8? Please confirm and reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:42:30
Query 'Unclear, 3 or 8? Please confirm and reconcile.' answered with 'updated, 8 ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:14:57
User opened query 'Unclear, 3 or 8? Please confirm and reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:43:45
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:43:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '8'	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '23 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:44:04
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:44:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '23 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User entered '1'	System	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User entered '1'	System	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User entered '804 (804)'	System	13 Apr 2021 13:47:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Apr 2021 08:56:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Apr 2021 08:56:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 13:50:34
User entered 'Prochlorperazine'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '5'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:42:45
User closed query 'Unit is mg/mL.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:42:43
Query 'Unit is mg/mL.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:10:46
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:10:42
User opened query 'Unit is mg/mL.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:44:27
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:44:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:42:46
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:10:42
User entered 'mg/ml' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:10:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '23 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '26 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User entered '1'	System	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User entered '1'	System	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:03
User entered '804 (804)'	System	13 Apr 2021 13:50:12

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCONATE SODIUM;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE, PRODUCTSYNONYM: PLASMALYTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 08:56:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 08:56:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 13:51:36
User entered 'PLASMA LYTE'	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '1000'	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mL (mL)'	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '23 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '23 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User entered '1'	System	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User entered '1'	System	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:07
User entered '804 (804)'	System	13 Apr 2021 13:51:11

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:52:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:52:57
Data point term sent to Coder	System	13 Apr 2021 13:52:36
User entered 'ACETAMINOPHEN'	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:43:02
User closed query 'Should be 1000/100' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:42:59
Query 'Should be 1000/100' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:04:20
User entered '1000/100' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:03:59
User opened query 'Should be 1000/100' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:45:31
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:45:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '1000'	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:43:06
User closed query 'Unit should be mg/mL' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:43:04
Query 'Unit should be mg/mL' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:04:25
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:03:59
User opened query 'Unit should be mg/mL' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:45:16
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:44:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:03:59
User entered 'mg/mL' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:03:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '23 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '23 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User entered '1'	System	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User entered '1'	System	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:11
User entered '804 (804)'	System	13 Apr 2021 13:51:58

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 13:20:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:20:58
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 13:53:37
User entered 'MORPHINE'	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:43:15
User closed query 'Should be 4mg/1mL. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:43:13
Query 'Should be 4mg/1mL. Please confirm.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:10:19
User entered '4/1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:10:11
User opened query 'Should be 4mg/1mL. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:46:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:46:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '4'	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:43:19
User closed query 'Should be 4mg/1mL. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:43:17
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:10:11
Query 'Should be 4mg/1mL. Please confirm.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:09:53
User opened query 'Should be 4mg/1mL. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:46:53
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:46:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:43:20
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:10:11
User entered 'mg/ml' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '23 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User entered '1'	System	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User entered '1'	System	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:14
User entered '804 (804)'	System	13 Apr 2021 13:53:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:57:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:57:06
Data point term sent to Coder	System	13 Apr 2021 13:55:38
User entered 'ZOFRAN'	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:43:28
User closed query 'Should be 4mg/2mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:43:26
Query 'Should be 4mg/2mL. Please reconcile.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:09:20
User entered '4/2' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:09:16
User opened query 'Should be 4mg/2mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:47:46
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:47:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '4'	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:43:31
User closed query 'Should be 4mg/2mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:43:29
Query 'Should be 4mg/2mL. Please reconcile.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:09:24
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:09:16
User opened query 'Should be 4mg/2mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:47:52
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:47:25
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:43:33
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:09:16
User entered 'mg/ml' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:09:16
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '27 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User entered empty.	System	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User entered empty.	System	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:18
User entered empty.	System	13 Apr 2021 13:54:52

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 14:56:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:56:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 13:56:39
User entered 'Prochlorperazine'	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'NAUSEA SECONDARY TO GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '5'	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User entered '1'	System	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User entered '1'	System	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:21
User entered '804 (804)'	System	13 Apr 2021 13:55:39

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 13:20:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:20:58
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 13:56:39
User entered 'MORPHINE'	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'PAIN SECONDARY TO GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:43:43
User closed query 'Should be 4mg/1mL. Please update.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:43:41
User entered '4/1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:08:01
Query 'Should be 4mg/1mL. Please update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:07:43
User opened query 'Should be 4mg/1mL. Please update.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:49:16
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:48:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '4'	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
User closed query 'Should be 4mg/1mL. Please update.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:43:45
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:08:01
Query 'Should be 4mg/1mL. Please update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:07:49
User opened query 'Should be 4mg/1mL. Please update.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:49:23
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:49:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:08:01
User entered 'mg/ml' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:08:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User entered '1'	System	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User entered '1'	System	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:09
User entered '804 (804)'	System	13 Apr 2021 13:56:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 14:56:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:56:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 13:57:42
User entered 'Prochlorperazine'	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'NAUSEA SECONDARY TO GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '5'	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:04:59
Query 'Per ConMed Log, should be 24Sep20.' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:04:57
User opened query 'Per ConMed Log, should be 24Sep20.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:03:54
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:03:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User entered '1'	System	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User entered '1'	System	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:12
User entered '804 (804)'	System	13 Apr 2021 13:57:21

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:00:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:00:00
Data point term sent to Coder	System	13 Apr 2021 13:58:42
User entered 'ACETAMINOPHEN'	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'PAIN SECONDARY TO GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '650'	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User entered '1'	System	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User entered '1'	System	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:03
User entered '804 (804)'	System	13 Apr 2021 13:58:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 13:25:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 13:25:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 13:59:43
User entered 'metronidazole'	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'gastritis'	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '500'	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User entered '1'	System	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User entered '1'	System	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:36:54
User entered '804 (804)'	System	13 Apr 2021 13:58:56

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 09:15:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 09:15:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 14:00:45
User entered 'CIPROFLOXACIN'	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'ANTIBIOTIC'	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '500'	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User entered '2'	System	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User entered '1'	System	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:56
User entered '804 (804)'	System	13 Apr 2021 14:00:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 13:25:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 13:25:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 14:02:46
User entered 'METRONIDAZOLE'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '500'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Q8HR'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User entered empty.	System	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User entered empty.	System	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:45
User entered empty.	System	13 Apr 2021 14:02:04

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:44:09
User closed query 'And / or + in between Cirpo & D5W' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:44:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:20:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:20:42
Data point term sent to Coder	System	13 Apr 2021 23:08:48
Query 'And / or + in between Cirpo & D5W' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:08:41
User entered 'CIPROFLOXACIN + D5W' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:08:35
User opened query 'And / or + in between Cirpo & D5W' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:14:50
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:14:22
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 14:05:48
User entered 'CIPROFLOXACIN d5w'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
User closed query 'correct to 400mg/200mL.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:44:15
Query 'correct to 400mg/200mL.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:08:45
User entered '400/200' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:08:35
User opened query 'correct to 400mg/200mL.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:14:03
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:30
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '400'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
User closed query 'Correct to 400mg/200mL.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:44:14
Query 'Correct to 400mg/200mL.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:08:49
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:08:35
User opened query 'Correct to 400mg/200mL.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:14:19
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:14:07
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:08:35
User entered 'mg/ml' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:08:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Q12hrs'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User entered empty.	System	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User entered empty.	System	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:49
User entered empty.	System	13 Apr 2021 14:05:05

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 13:25:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 13:25:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 14:06:49
User entered 'metronidazole'	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'gastritis'	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '500'	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
User closed query 'Per ConMed, should be q8hrs or 3 times daily. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:44:22
Query 'Per ConMed, should be q8hrs or 3 times daily. Please reconcile.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:07:24
User entered 'three times daily (TID)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:07:20
User opened query 'Per ConMed, should be q8hrs or 3 times daily. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:18:52
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:16:53
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'four times daily (QID)'	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User entered '3'	System	13 Apr 2021 23:07:20
User entered '4'	System	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User entered '1'	System	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:34:53
User entered '804 (804)'	System	13 Apr 2021 14:06:15

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 13:20:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:20:58
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 14:07:51
User entered 'morphine'	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'pain secondary to gastritis'	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
User closed query 'Should be 2mg/1mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:44:27
User entered '2/1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:06:39
Query 'Should be 2mg/1mL. Please reconcile.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:06:14
User opened query 'Should be 2mg/1mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:19:22
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:19:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '2'	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
User closed query 'Should be 2mg/1mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:44:29
Query 'Should be 2mg/1mL. Please reconcile.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:06:44
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:06:39
User opened query 'Should be 2mg/1mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:19:28
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:19:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:06:39
User entered 'mg/ml' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'four times daily (QID)'	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
User closed query 'Subject received 2mg morphine injection on 27Sep. Please extend end date to 27Sep20.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:44:33
Query 'Subject received 2mg morphine injection on 27Sep. Please extend end date to 27Sep20.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:06:58
User entered '27 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:06:39
User opened query 'Subject received 2mg morphine injection on 27Sep. Please extend end date to 27Sep20.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:20:27
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:16:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '26 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User entered '4'	System	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User entered '1'	System	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:49
User entered '804 (804)'	System	13 Apr 2021 14:07:25

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 08:02:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:02:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 14:08:51
User entered 'zofran'	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'nausea secondary to gastritis'	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
User closed query 'Should be 4mg/2mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:44:40
Query 'Should be 4mg/2mL. Please reconcile.' answered with 'update' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:05:44
User entered '4/2' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:05:39
User opened query 'Should be 4mg/2mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:20:00
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:19:48
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '4'	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
User closed query 'Should be 2mg/1mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:44:42
Query 'Should be 2mg/1mL. Please reconcile.' answered with 'update' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:05:49
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:05:39
User opened query 'Should be 2mg/1mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:20:05
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:19:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:05:39
User entered 'mg/ml' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:05:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '26 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User entered empty.	System	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User entered empty.	System	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:46
User entered empty.	System	13 Apr 2021 14:08:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:11:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:11:00
Data point term sent to Coder	System	13 Apr 2021 14:09:53
User entered 'acetaminophen'	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'pain secondary to gastritis'	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '1000'	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '26 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '26 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User entered '1'	System	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User entered '1'	System	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:43
User entered '804 (804)'	System	13 Apr 2021 14:09:19

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCOSE;SODIUM CHLORIDE, PRODUCTSYNONYM: DEXTROSE;SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Apr 2021 13:49:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	15 Apr 2021 13:49:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 14:11:54
User entered 'D5W (Dextrose 5% Water) NACL 0.45% IV Fluid'	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Fluids'	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '100'	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mL (mL)'	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '26 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '26 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User entered '1'	System	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User entered '1'	System	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:40
User entered '804 (804)'	System	13 Apr 2021 14:11:08

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 13:01:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 13:01:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 14:12:55
User entered 'omeprazole'	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'nausea secondary to gastritis'	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '40'	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User entered '1'	System	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User entered '1'	System	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:37
User entered '804 (804)'	System	13 Apr 2021 14:12:18

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 13:20:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:20:58
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 14:13:57
User entered 'morphine'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'pain secondary to gastritis'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
User closed query 'Should be 4mg/1mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:45:05
Query 'Should be 4mg/1mL. Please reconcile.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:05:08
User entered '4/1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:05:02
User opened query 'Should be 4mg/1mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:21:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:21:05
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '4'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
User closed query 'Should be 4mg/1mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:45:07
Query 'Should be 4mg/1mL. Please reconcile.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 23:05:12
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:05:02
User opened query 'Should be 4mg/1mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:21:26
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:21:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:45:18
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 23:05:02
User entered 'mg/ml' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 23:05:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Q8HR PRN'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '27 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '29 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User entered empty.	System	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User entered empty.	System	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:29
User entered empty.	System	13 Apr 2021 14:13:20

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 12:52:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 12:52:58
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 14:14:58
User entered 'OXYCODONE'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'PAIN SECONDARY GASTRITIS'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '5'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'bid prn'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '29 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User entered empty.	System	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User entered empty.	System	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:26
User entered empty.	System	13 Apr 2021 14:14:27

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 12:52:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 12:52:58
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:39:47
Data point term sent to Coder	System	13 Apr 2021 14:15:59
User entered 'oxycodone'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'pain secondary to gastritis'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '5'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'other (OTHER)'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'tid prn'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '29 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:31:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:39:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User entered empty.	System	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User entered empty.	System	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 10:33:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:35:22
User entered empty.	System	13 Apr 2021 14:15:13

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:33:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:06:44
User closed query 'Please add echo, MRI, CT (head, sinus) and EKG.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 20:06:42
Query 'Please add echo, MRI, CT (head, sinus) and EKG.' answered with 'All have been added. ' (Site from CRA).	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:13:20
User opened query 'Please add echo, MRI, CT (head, sinus) and EKG.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:25:25
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	30 Dec 2020 14:16:27

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:30:05
User entered '31 Oct 2020' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	30 Dec 2020 14:18:30
User entered '01 Nov 2020'	Atanas Filev (b) (4) (b) (4)	30 Dec 2020 14:18:05

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 23:06:28
User entered 'CTA PE PROTOCOL W WO IV CONTRAST for pericarditis' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	06 Apr 2021 22:35:48
Query 'Scan occurred after the Gastritis. Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 22:29:30
User closed query 'Per CDM: Kindly confirm for which Adverse event this procedure was performed and consider to update same on the corresponding AE page. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:46:31
User opened query 'Scan occurred after the Gastritis. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:53:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 19:53:13
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:50:43
Query 'Per CDM: Kindly confirm for which Adverse event this procedure was performed and consider to update same on the corresponding AE page. Thank you.' answered with 'Linked to Gastritis with intractable vomiting. AE page updated.' (Site from DM).	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:07:08
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 18:30:07
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 18:30:05
User opened query 'Per CDM: Kindly confirm for which Adverse event this procedure was performed and consider to update same on the corresponding AE page. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 17:28:03

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CTA PE Protocol W WO IV Contrast'	Atanas Filev (b) (4) (b) (4)	30 Dec 2020 14:18:05

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:30:05
User entered 'Adverse Event (AE)'	Atanas Filev (b) (4) (b) (4)	30 Dec 2020 14:18:05

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:33:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:30:05
User entered empty.	Atanas Filev (b) (4) (b) (4)	30 Dec 2020 14:18:05

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:30:05
User entered '01 Nov 2020'	Atanas Filev (b) (4) (b) (4)	30 Dec 2020 14:19:18

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'Gastritis occurred prior to 01Nov20. Please confirm and update if needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 23:06:34
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 23:06:32
Query 'Gastritis occurred prior to 01Nov20. Please confirm and update if needed.' answered with 'Updated' (Site from CRA).	Atanas Filev (b) (4) (b) (4)	06 Apr 2021 22:33:48
User entered 'PHARMACOLOGICAL NUCLEAR CARDIAC STRESS TEST for pericarditis' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	06 Apr 2021 22:33:42
User closed query 'Per CDM: Kindly confirm for which Adverse event this procedure was performed and consider to update same on the corresponding AE page. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:46:39
User opened query 'Gastritis occurred prior to 01Nov20. Please confirm and update if needed.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 19:50:55
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:50:50
Query 'Per CDM: Kindly confirm for which Adverse event this procedure was performed and consider to update same on the corresponding AE page. Thank you. ' answered with 'Linked to Gastritis with intractable vomiting. AE page updated. ' (Site from DM).	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:06:59
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 18:30:15
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 18:30:05

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Kindly confirm for which Adverse event this procedure was performed and consider to update same on the corresponding AE page. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 17:28:22
User entered 'Pharmacological Nuclear Cardiac Stress Test'	Atanas Filev (b) (4)	30 Dec 2020 14:19:18

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:30:05
User entered 'Adverse Event (AE)'	Atanas Filev (b) (4) (b) (4)	30 Dec 2020 14:19:18

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:33:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:30:05
User entered empty.	Atanas Filev (b) (4) (b) (4)	30 Dec 2020 14:19:18

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:55:15
User entered '02 Nov 2020'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:10:30

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:55:36
User entered 'Transthoracic Echo Report (2D with doppler and color flow)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:10:30

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:55:38
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	10 Feb 2021 18:10:39
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	10 Feb 2021 18:10:30
User entered 'Adverse Event (AE)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:10:30

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:33:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:55:41
User entered empty; reason for change Data Entry Error	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:10:39
User entered 'Linked to Gastritis with intractable vomiting.'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:10:30

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:56:02
User entered '01 Nov 2020'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:11:19

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 23:06:41
DataPoint Un-verified.	Atanas Filev (b) (4)	06 Apr 2021 22:36:23
User entered 'MRI OF THE BRAIN WITHOUT CONTRAST for PERICARDITIS' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	06 Apr 2021 22:36:23
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:56:04
User entered 'MRI of the Brain without Contrast'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:11:19

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query 'PER CDM: Indication was recorded as AE. However, no related AE recorded in the above mentioned time period. Please review and update as appropriate. Thank you.' (Site from DM). Query 'PER CDM: Indication was recorded as AE. However, no related AE recorded in the above mentioned time period. Please review and update as appropriate. Thank you.' answered with 'Updated. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 10:45:27
User opened query 'PER CDM: Indication was recorded as AE. However, no related AE recorded in the above mentioned time period. Please review and update as appropriate. Thank you.' answered with 'Updated. ' (Site from DM).	Atanas Filev (b) (4) (b) (4)	06 Apr 2021 22:36:29
User opened query 'PER CDM: Indication was recorded as AE. However, no related AE recorded in the above mentioned time period. Please review and update as appropriate. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 06:11:35
	(b) (4), (b) (6)	10 Feb 2021 19:56:05
User entered 'Adverse Event (AE)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:11:19

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:33:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:56:08
User entered empty.	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:11:19

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:33:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query ' PER CDM: Indication was recorded as AE. However, no related AE recorded in the above mentioned time period. Please review and update as appropriate. Thank you.' (Site from DM). Query ' PER CDM: Indication was recorded as AE. However, no related AE recorded in the above mentioned time period. Please review and update as appropriate. Thank you.' answered with 'Updated. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 10:45:34
User opened query ' PER CDM: Indication was recorded as AE. However, no related AE recorded in the above mentioned time period. Please review and update as appropriate. Thank you.' (Site from DM).	Atanas Filev (b) (4) (b) (4)	06 Apr 2021 22:37:18
User opened query ' PER CDM: Indication was recorded as AE. However, no related AE recorded in the above mentioned time period. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 06:11:44
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:56:23
User entered '01 Nov 2020'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:12:11

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 23:06:47
DataPoint Un-verified.	Atanas Filev (b) (4)	06 Apr 2021 22:36:42
User entered 'CT OF THE SINUS WITHOUT CONTRAST for PERICARDITIS' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	06 Apr 2021 22:36:42
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:56:25
User entered 'CT of the Sinus without Contrast'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:12:11

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:56:26
User entered 'Adverse Event (AE)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:12:11

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:33:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:56:28
User entered empty.	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:12:11

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
User closed query ' PER CDM: Indication was recorded as AE. However, no related AE recorded in the above mentioned time period. Please review and update as appropriate. Thank you.' (Site from DM). Query ' PER CDM: Indication was recorded as AE. However, no related AE recorded in the above mentioned time period. Please review and update as appropriate. Thank you.' answered with 'Updated. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 10:45:38
User opened query ' PER CDM: Indication was recorded as AE. However, no related AE recorded in the above mentioned time period. Please review and update as appropriate. Thank you.' (Site from DM).	Atanas Filev (b) (4) (b) (4)	06 Apr 2021 22:37:40
User opened query ' PER CDM: Indication was recorded as AE. However, no related AE recorded in the above mentioned time period. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 06:11:55
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:56:35
User entered '01 Nov 2020'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:12:52

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 23:06:51
DataPoint Un-verified.	Atanas Filev (b) (4)	06 Apr 2021 22:37:28
User entered 'CT OF THE HEAD WITHOUT CONTRAST for PERICARDITIS' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	06 Apr 2021 22:37:28
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:56:36
User entered 'CT of the head without contrast'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:12:52

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:56:38
User entered 'Adverse Event (AE)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:12:52

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:33:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:56:40
User entered empty.	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:12:52

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:57:08
User entered '31 Oct 2020'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:13:14

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 23:06:54
DataPoint Un-verified.	Atanas Filev (b) (4)	06 Apr 2021 22:37:48
User entered '12 LEAD EKG for PERICARDITIS'	(b) (4)	
reason for change: Data Entry Error	Atanas Filev (b) (4)	06 Apr 2021 22:37:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 19:57:10
User entered '12 Lead EKG'	Atanas Filev (b) (4)	10 Feb 2021 18:13:14
	(b) (4)	

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:57:13
User entered 'Adverse Event (AE)'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:13:14

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:33:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:57:15
User entered empty.	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 18:13:14

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 23:06:59
User entered '28 Sep 2020'	Atanas Filev (b) (4) (b) (4)	06 Apr 2021 23:04:31

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:33:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 23:07:00
User entered 'Esophagogastroduodenoscopy for Gastritis'	Atanas Filev (b) (4) (b) (4)	06 Apr 2021 23:04:31

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:33:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 23:07:02
User entered 'Adverse Event (AE)'	Atanas Filev (b) (4) (b) (4)	06 Apr 2021 23:04:31

US3952033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:33:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 23:07:04
User entered empty.	Atanas Filev (b) (4) (b) (4)	06 Apr 2021 23:04:31

US3952033

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:33:44

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:41:23
User closed query 'PER CDM: Re-Query: Per previous response it was reported that "Date of dosing discontinuation is 06Oct2020 as that was the date the subject tested positive for Covid-19". However, per COVID 19 Diagnostic test page test was performed on 08-OCT-20. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:36:09
Query 'PER CDM: Re-Query: Per previous response it was reported that "Date of dosing discontinuation is 06Oct2020 as that was the date the subject tested positive for Covid-19". However, per COVID 19 Diagnostic test page test was performed on 08-OCT-20. Please review and update as appropriate. Thank you.' answered with 'Patient had an non-study positive COVID test on 06 Oct 2020 and a study positive COVID test on 08 Oct 2020. Regardless decision to discontinue dosing was made on 08 Oct 2020. Updated EDC. ' (Site from DM).	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:30:26
User entered '08 Oct 2020' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:30:22
User opened query 'PER CDM: Re-Query: Per previous response it was reported that "Date of dosing discontinuation is 06Oct2020 as that was the date the subject tested positive for Covid-19". However, per COVID 19 Diagnostic test page test was performed on 08-OCT-20. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 08:24:33
User closed query 'Per CDM: Date of dosing discontinuation date was recorded as 06-OCT-20 due to Covid-19. However, in symptom log Day 1 was reported as 08-OCT-20. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 08:24:33

US3952033

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:33:44

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Date of dosing discontinuation date was recorded as 06-OCT-20 due to Covid-19. However, in symptom log Day 1 was reported as 08-OCT-20. Please review and update as appropriate. Thank you. ' answered with 'Date of dosing discontinuation is 06Oct2020 as that was the date the subject tested positive for Covid-19.' (Site from DM). User opened query 'Per CDM: Date of dosing discontinuation date was recorded as 06-OCT-20 due to Covid-19. However, in symptom log Day 1 was reported as 08-OCT-20. Please review and update as appropriate. Thank you. ' (Site from DM). User entered '06 Oct 2020'	Nick Bart (b) (4) (b) (4), (b) (6) Nick Bart (b) (4)	04 Dec 2020 16:13:51 11 Nov 2020 15:01:43 10 Nov 2020 21:52:27

US3952033

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:33:44

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:41:28
User closed query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:25:47
Query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	02 Dec 2020 17:19:18
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:19:14
User opened query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 17:01:51
User entered 'AE (specify) (ADVERSE EVENT)'	Nick Bart (b) (4)	10 Nov 2020 21:52:27

US3952033

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:33:44

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:41:30
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	02 Dec 2020 17:19:14
User entered 'Covid-19 Positive'	Nick Bart (b) (4)	10 Nov 2020 21:52:27

US3952033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:33:44

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:41:43
User entered '20 Jan 2021'	Atanas Filev (b) (4) (b) (4)	20 Jan 2021 19:24:53

US3952033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:33:44

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:36
User signature succeeded.	Mimi Van Der Leden	19 Apr 2021 20:52:19
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:06:13
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 20:06:13
User entered 'Physician decision (specify) (PHYSICIAN DECISION)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 20:06:13
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 19:41:43
User entered 'Other (OTHER)'	Atanas Filev (b) (4)	20 Jan 2021 19:24:53

US3952033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:33:44

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User closed query 'Per CDM: It appears that the reason for discontinuation was medically related. If the PI deemed the subject medically unstable for continuing then please confirm Reason for Discontinuation should be Physician Decision.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:31:25
Query 'Per CDM: It appears that the reason for discontinuation was medically related. If the PI deemed the subject medically unstable for continuing then please confirm Reason for Discontinuation should be Physician Decision.' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 20:06:30
User opened query 'Per CDM: It appears that the reason for discontinuation was medically related. If the PI deemed the subject medically unstable for continuing then please confirm Reason for Discontinuation should be Physician Decision.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 15:28:15
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:41:43
User entered 'Not medically stable to proceed to open label vaccine. Will get outside EUA leading to withdraw.'	Atanas Filev (b) (4) (b) (4)	20 Jan 2021 19:24:53

US3952033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:33:44

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:41:43
User entered empty.	Atanas Filev (b) (4) (b) (4)	20 Jan 2021 19:24:53

US3952033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:33:44

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:41:43
User entered empty.	Atanas Filev (b) (4) (b) (4)	20 Jan 2021 19:24:53

US3952033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:33:44

[Date of death \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:41:43
User entered empty.	Atanas Filev (b) (4) (b) (4)	20 Jan 2021 19:24:53

US3952033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:33:44

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:41:43
User entered empty.	Atanas Filev (b) (4) (b) (4)	20 Jan 2021 19:24:53

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'USA-US215-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 14:50:44
Un-reviewed for Safety.	System	16 Oct 2020 20:50:34
User entered 'No (N)'	System	16 Oct 2020 20:50:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Un-reviewed for Safety.	System	12 Oct 2020 14:21:55
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered 'Yes (Y)'	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Mimi'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Van Der Leden'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '15201 Shady Grove Dr'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Rockville'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:45:47
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:36:25
User entered empty.	System	11 Nov 2020 14:28:27
Un-reviewed for Safety.	Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Un-verified.	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
User entered 'Maryland' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered empty.	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'Maryland'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:37:51

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '20850'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'US'	(b) (4) System	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '7'	System	11 Feb 2021 16:48:59
User entered '6'	System	22 Jan 2021 15:20:21
User entered '5'	System	03 Dec 2020 19:24:07
User entered '4'	System	11 Nov 2020 15:36:50
User entered '3'	System	19 Oct 2020 14:50:58
Signature has been broken.	System	12 Oct 2020 14:22:51
User entered '2'	System	12 Oct 2020 14:22:51
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered '1'	(b) (4)	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'USA-US215-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 14:50:44
Un-reviewed for Safety.	System	16 Oct 2020 20:50:34
User entered 'No (N)'	System	16 Oct 2020 20:50:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Un-reviewed for Safety.	System	12 Oct 2020 14:21:55
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered 'Yes (Y)'	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Mimi'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Van Der Leden'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '15201 Shady Grove Dr'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Rockville'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:45:47
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:36:25
User entered empty.	System	11 Nov 2020 14:28:27
Un-reviewed for Safety.	Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Un-verified.	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
User entered 'Maryland' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered empty.	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'Maryland'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:37:51

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '20850'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'US'	(b) (4) System	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '7'	System	11 Feb 2021 16:48:59
User entered '6'	System	22 Jan 2021 15:20:21
User entered '5'	System	03 Dec 2020 19:24:07
User entered '4'	System	11 Nov 2020 15:36:50
User entered '3'	System	19 Oct 2020 14:50:58
Signature has been broken.	System	12 Oct 2020 14:22:51
User entered '2'	System	12 Oct 2020 14:22:51
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered '1'	(b) (4)	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:33:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:09:39
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered '29/Sep/2020 10:21'	(b) (4) System	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:33:44

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:27
User closed query 'Per source AE 3 page, there was follow-up information. Please enter.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:33:20
Query 'Per source AE 3 page, there was follow-up information. Please enter.' answered with 'There is nowhere on AE source page to report follow up information. Any follow-up information available will be recorded upon receipt of medical records.' (Site from CRA).	Nick Bart (b) (4)	10 Nov 2020 19:53:44
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:37
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
User opened query 'Per source AE 3 page, there was follow-up information. Please enter.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 20:07:19
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'USA-US215-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 14:50:44
Un-reviewed for Safety.	System	16 Oct 2020 20:50:34
User entered 'No (N)'	System	16 Oct 2020 20:50:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Un-reviewed for Safety.	System	12 Oct 2020 14:21:55
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered 'Yes (Y)'	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Mimi'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Van Der Leden'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '15201 Shady Grove Dr'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Rockville'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:45:47
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:36:25
User entered empty.	System	11 Nov 2020 14:28:27
Un-reviewed for Safety.	Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Un-verified.	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
User entered 'Maryland' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered empty.	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'Maryland'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:37:51

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '20850'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'US'	(b) (4) System	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '7'	System	11 Feb 2021 16:48:59
User entered '6'	System	22 Jan 2021 15:20:21
User entered '5'	System	03 Dec 2020 19:24:07
User entered '4'	System	11 Nov 2020 15:36:50
User entered '3'	System	19 Oct 2020 14:50:58
Signature has been broken.	System	12 Oct 2020 14:22:51
User entered '2'	System	12 Oct 2020 14:22:51
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered '1'	(b) (4)	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:33:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:09:51
User entered '12/Oct/2020 14:22'	System	12 Oct 2020 14:22:51

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:33:44

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 14:50:44
User entered '1'	(b) (4), (b) (6)	12 Oct 2020 14:22:51

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'USA-US215-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 14:50:44
Un-reviewed for Safety.	System	16 Oct 2020 20:50:34
User entered 'No (N)'	System	16 Oct 2020 20:50:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Un-reviewed for Safety.	System	12 Oct 2020 14:21:55
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered 'Yes (Y)'	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Mimi'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Van Der Leden'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '15201 Shady Grove Dr'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Rockville'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:45:47
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:36:25
User entered empty.	System	11 Nov 2020 14:28:27
Un-reviewed for Safety.	Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Un-verified.	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
User entered 'Maryland' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered empty.	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'Maryland'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:37:51

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '20850'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'US'	(b) (4) System	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '7'	System	11 Feb 2021 16:48:59
User entered '6'	System	22 Jan 2021 15:20:21
User entered '5'	System	03 Dec 2020 19:24:07
User entered '4'	System	11 Nov 2020 15:36:50
User entered '3'	System	19 Oct 2020 14:50:58
Signature has been broken.	System	12 Oct 2020 14:22:51
User entered '2'	System	12 Oct 2020 14:22:51
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered '1'	(b) (4)	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:33:44

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:14:05
User entered '19/Oct/2020 14:50'	System	19 Oct 2020 14:50:58

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:33:44

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:36:25
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User entered '1'	(b) (4), (b) (6)	19 Oct 2020 14:50:58

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'USA-US215-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 14:50:44
Un-reviewed for Safety.	System	16 Oct 2020 20:50:34
User entered 'No (N)'	System	16 Oct 2020 20:50:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Un-reviewed for Safety.	System	12 Oct 2020 14:21:55
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered 'Yes (Y)'	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Mimi'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Van Der Leden'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '15201 Shady Grove Dr'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Rockville'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:45:47
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:36:25
User entered empty.	System	11 Nov 2020 14:28:27
Un-reviewed for Safety.	Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Un-verified.	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
User entered 'Maryland' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered empty.	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'Maryland'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:37:51

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '20850'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'US'	(b) (4) System	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '7'	System	11 Feb 2021 16:48:59
User entered '6'	System	22 Jan 2021 15:20:21
User entered '5'	System	03 Dec 2020 19:24:07
User entered '4'	System	11 Nov 2020 15:36:50
User entered '3'	System	19 Oct 2020 14:50:58
Signature has been broken.	System	12 Oct 2020 14:22:51
User entered '2'	System	12 Oct 2020 14:22:51
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered '1'	(b) (4)	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:33:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 18:55:59
User entered '11/Nov/2020 10:36'	System	11 Nov 2020 15:36:50

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:33:44

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:23:52
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:56:03
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 15:36:50

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'USA-US215-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 14:50:44
Un-reviewed for Safety.	System	16 Oct 2020 20:50:34
User entered 'No (N)'	System	16 Oct 2020 20:50:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Un-reviewed for Safety.	System	12 Oct 2020 14:21:55
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered 'Yes (Y)'	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Mimi'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Van Der Leden'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '15201 Shady Grove Dr'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Rockville'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:45:47
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:36:25
User entered empty.	System	11 Nov 2020 14:28:27
Un-reviewed for Safety.	Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Un-verified.	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
User entered 'Maryland' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered empty.	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'Maryland'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:37:51

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '20850'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'US'	(b) (4) System	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '7'	System	11 Feb 2021 16:48:59
User entered '6'	System	22 Jan 2021 15:20:21
User entered '5'	System	03 Dec 2020 19:24:07
User entered '4'	System	11 Nov 2020 15:36:50
User entered '3'	System	19 Oct 2020 14:50:58
Signature has been broken.	System	12 Oct 2020 14:22:51
User entered '2'	System	12 Oct 2020 14:22:51
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered '1'	(b) (4)	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:33:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:45:52
User entered '03/Dec/2020 14:24'	System	03 Dec 2020 19:24:07

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:33:44

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:45:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:20:07
User entered '1'	(b) (4), (b) (6)	03 Dec 2020 19:24:07

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'USA-US215-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 14:50:44
Un-reviewed for Safety.	System	16 Oct 2020 20:50:34
User entered 'No (N)'	System	16 Oct 2020 20:50:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Un-reviewed for Safety.	System	12 Oct 2020 14:21:55
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered 'Yes (Y)'	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Mimi'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Van Der Leden'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '15201 Shady Grove Dr'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Rockville'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:45:47
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:36:25
User entered empty.	System	11 Nov 2020 14:28:27
Un-reviewed for Safety.	Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Un-verified.	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
User entered 'Maryland' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered empty.	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'Maryland'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:37:51

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '20850'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'US'	(b) (4) System	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '7'	System	11 Feb 2021 16:48:59
User entered '6'	System	22 Jan 2021 15:20:21
User entered '5'	System	03 Dec 2020 19:24:07
User entered '4'	System	11 Nov 2020 15:36:50
User entered '3'	System	19 Oct 2020 14:50:58
Signature has been broken.	System	12 Oct 2020 14:22:51
User entered '2'	System	12 Oct 2020 14:22:51
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered '1'	(b) (4)	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:33:44

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:45:52
User entered '22/Jan/2021 15:20'	System	22 Jan 2021 15:20:21

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:33:44

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:48:33
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:45:52
User entered '1'	(b) (4), (b) (6)	22 Jan 2021 15:20:21

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'USA-US215-2020-MRNA-1273-P301000001'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Yes (Y)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 14:50:44
Un-reviewed for Safety.	System	16 Oct 2020 20:50:34
User entered 'No (N)'	System	16 Oct 2020 20:50:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Un-reviewed for Safety.	System	12 Oct 2020 14:21:55
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered 'Yes (Y)'	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'No (N)'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Mimi'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Van Der Leden'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '15201 Shady Grove Dr'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered 'Rockville'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:45:47
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:55:44
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:36:25
User entered empty.	System	11 Nov 2020 14:28:27
Un-reviewed for Safety.	Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Un-verified.	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
User entered 'Maryland' reason for change: Data Entry Error	(b) (4) Atanas Filev (b) (4)	06 Nov 2020 14:10:51
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
Signature has been broken.	System	12 Oct 2020 14:21:55
User entered empty.	System	12 Oct 2020 14:21:55
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'Maryland'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:37:51

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:21:27
User entered '20850'	System	29 Sep 2020 14:21:13

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 14:14:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:22:32
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered 'US'	(b) (4) System	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '7'	System	11 Feb 2021 16:48:59
User entered '6'	System	22 Jan 2021 15:20:21
User entered '5'	System	03 Dec 2020 19:24:07
User entered '4'	System	11 Nov 2020 15:36:50
User entered '3'	System	19 Oct 2020 14:50:58
Signature has been broken.	System	12 Oct 2020 14:22:51
User entered '2'	System	12 Oct 2020 14:22:51
User signature succeeded.	Mimi Van Der Leden	29 Sep 2020 14:47:25
User entered '1'	(b) (4)	29 Sep 2020 14:21:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:33:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:10:12
User entered '11/Feb/2021 10:48'	System	11 Feb 2021 16:48:59

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:33:44

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:10:14
User entered '1'	(b) (4), (b) (6)	11 Feb 2021 16:48:59

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'USA-US215-2020-MRNA-1273-P301000004'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Yes (Y)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Yes (Y)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Mimi'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Van Der Leden'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered '15201 Shady Grove Dr'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Rockville'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 14:28:48
User entered empty.	System	11 Nov 2020 14:28:27
User entered 'Maryland'	Atanas Filev (b) (4) (b) (4)	06 Nov 2020 14:10:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered '20850'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'US'	System	05 Nov 2020 17:03:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '3'	System	21 Nov 2020 02:17:19
User entered '2'	System	11 Nov 2020 14:29:16
User entered '1'	System	05 Nov 2020 17:03:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'USA-US215-2020-MRNA-1273-P301000004'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Yes (Y)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Yes (Y)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Mimi'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Van Der Leden'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered '15201 Shady Grove Dr'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Rockville'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 14:28:48
User entered empty.	System	11 Nov 2020 14:28:27
User entered 'Maryland'	Atanas Filev (b) (4) (b) (4)	06 Nov 2020 14:10:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered '20850'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'US'	System	05 Nov 2020 17:03:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '3'	System	21 Nov 2020 02:17:19
User entered '2'	System	11 Nov 2020 14:29:16
User entered '1'	System	05 Nov 2020 17:03:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:33:44

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:46:04
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 22:42:25
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:42:05
User entered '05/Nov/2020 17:03'	System	05 Nov 2020 17:03:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:33:44

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:46:04
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 22:42:27
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 17:03:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'USA-US215-2020-MRNA-1273-P301000004'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Yes (Y)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Yes (Y)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Mimi'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Van Der Leden'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered '15201 Shady Grove Dr'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Rockville'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 14:28:48
User entered empty.	System	11 Nov 2020 14:28:27
User entered 'Maryland'	Atanas Filev (b) (4) (b) (4)	06 Nov 2020 14:10:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered '20850'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'US'	System	05 Nov 2020 17:03:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '3'	System	21 Nov 2020 02:17:19
User entered '2'	System	11 Nov 2020 14:29:16
User entered '1'	System	05 Nov 2020 17:03:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:33:44

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:46:04
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 22:42:31
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:42:05
User entered '11/Nov/2020 09:29'	System	11 Nov 2020 14:29:16

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:33:44

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:46:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 02:16:51
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 22:42:33
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:42:05
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 14:29:16

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'USA-US215-2020-MRNA-1273-P301000004'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Yes (Y)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Yes (Y)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'No (N)'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Mimi'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Van Der Leden'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered '15201 Shady Grove Dr'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'Rockville'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 14:28:48
User entered empty.	System	11 Nov 2020 14:28:27
User entered 'Maryland'	Atanas Filev (b) (4) (b) (4)	06 Nov 2020 14:10:33

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered '20850'	System	05 Nov 2020 17:02:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:42:05
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 17:06:24
User entered 'US'	System	05 Nov 2020 17:03:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '3'	System	21 Nov 2020 02:17:19
User entered '2'	System	11 Nov 2020 14:29:16
User entered '1'	System	05 Nov 2020 17:03:57

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:33:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:46:04
User entered '20/Nov/2020 21:17'	System	21 Nov 2020 02:17:19

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:33:44

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:46:04
User entered '1'	(b) (4), (b) (6)	21 Nov 2020 02:17:19

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
Query 'SAE form is present, but no new corresponding SAE. Please confirm and inactivate page if needed.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 15:16:08
User opened query 'SAE form is present, but no new corresponding SAE. Please confirm and inactivate page if needed.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 15:02:14
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:52
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'USA-US215-2020-MRNA-1273-P301000007'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:58
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:55
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:03
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:04
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:06
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:10
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:12
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'Mimi'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:14
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'Van Der Leden'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:45
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered '15201 Shady Grove Dr'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:17
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'Rockville'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:28
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:38
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered '20850'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:30:19
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:26
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:41
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
User entered 'US'	System	03 Dec 2020 19:20:42

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '2'	System	22 Dec 2020 17:30:43
User entered '1'	System	03 Dec 2020 19:20:42

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
Query 'SAE form is present, but no new corresponding SAE. Please confirm and inactivate page if needed.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 15:16:08
User opened query 'SAE form is present, but no new corresponding SAE. Please confirm and inactivate page if needed.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 15:02:14
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:52
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'USA-US215-2020-MRNA-1273-P301000007'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:58
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:55
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:03
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:04
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:06
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:10
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:12
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'Mimi'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:14
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'Van Der Leden'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:45
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered '15201 Shady Grove Dr'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:17
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'Rockville'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:28
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:38
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered '20850'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:30:19
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:26
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:41
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
User entered 'US'	System	03 Dec 2020 19:20:42

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '2'	System	22 Dec 2020 17:30:43
User entered '1'	System	03 Dec 2020 19:20:42

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:33:44

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:20
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:35
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
User entered '03/Dec/2020 14:20'	System	03 Dec 2020 19:20:42

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:33:44

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:30:19
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:22
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:34
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
User entered '1'	(b) (4), (b) (6)	03 Dec 2020 19:20:42

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
Query 'SAE form is present, but no new corresponding SAE. Please confirm and inactivate page if needed.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 15:16:08
User opened query 'SAE form is present, but no new corresponding SAE. Please confirm and inactivate page if needed.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 15:02:14
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:52
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'USA-US215-2020-MRNA-1273-P301000007'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:58
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:55
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:03
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:04
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:06
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:10
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'No (N)'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:12
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'Mimi'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:14
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'Van Der Leden'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:45
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered '15201 Shady Grove Dr'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:17
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered 'Rockville'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:28
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:38
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:20:29
User entered '20850'	System	03 Dec 2020 19:16:30

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:30:19
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:16:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:01:26
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:00:41
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:59:06
User entered 'US'	System	03 Dec 2020 19:20:42

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:33:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User entered '2'	System	22 Dec 2020 17:30:43
User entered '1'	System	03 Dec 2020 19:20:42

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:33:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:10:33
User entered '22/Dec/2020 09:30'	System	22 Dec 2020 17:30:43

US3952033

Folder: SAE USA-US215-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:33:44

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:20:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:10:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:10:33
User entered '1'	(b) (4), (b) (6)	22 Dec 2020 17:30:43