

US3952004 (Prod: Synexus - Optimal Research - Rockville)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:32:34

All time stamps listed in this document are displayed in GMT

US3952004

Form: Participant Creation

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

[Participant ID](#)

US3952004

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

US3952004

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 07 Apr 2021 21:35:09

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Date of Informed Consent (<i>dd MMM yyyy</i>)	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Condition	HYPERTENSION
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)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Condition	GLAUCOMA
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) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1956
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 1956
Start Year (derived)	1956
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Condition	GERD
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)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Condition	HYPERLIPIDEMIA
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) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Condition	HERNIATED LUMBAR DISKS
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)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Condition	OSTEOARTHRITIS
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)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Condition	RIGHT EYE CATARACT
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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Condition	ROSACEA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952004

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Condition	DEGENERATIVE SPONDYLOLISTHESIS
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)	

US3952004

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Condition	RIGHT EYE CATARACT SURGERY
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

US3952004

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	11:11 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:11
Height (xxx.x)	63.0 in
Weight (xxx.x)	168.0 lb
BMI (xxx.x)	29.82209 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	35.9 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	60 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)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 07 Apr 2021 21:35:09

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Date of assessment (dd MMM yyyy) 28 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 1990

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

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 True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 07 Apr 2021 21:35:09

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 189574

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Height

Weight

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Height	
Weight	
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	09:09 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 09:09
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Height	
Weight	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	11:47 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 11:47
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

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) 04 SEP 2020

What was the treatment time? (00:00-23:59) 10:53 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 10:53

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 SEP 2020

Collection time (00:00-23:59)

09:50 (24 HR)

Collection date and time (derived)

04 SEP 2020 09:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:55	04 SEP 2020 09:55
Nasopharyngeal Swab 2	No		

US3952004

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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

98.2 °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 04 SEP 2020 11:50

PC Open Date & Time 04 SEP 2020 11:13

PC Close Date & Time 04 SEP 2020 13:43

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp	04 SEP 2020 14:40
PC Open Date & Time	04 SEP 2020 14:38
PC Close Date & Time	05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 18:58

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

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):

PC Time Stamp

06 SEP 2020 18:51

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 18:59

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

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

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):

PC Time Stamp

08 SEP 2020 19:03

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

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):

PC Time Stamp

09 SEP 2020 19:39

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 19:09

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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

04 SEP 2020 11:53

PC Open Date & Time

04 SEP 2020 11:13

PC Close Date & Time

04 SEP 2020 13:43

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 14:41

PC Open Date & Time

04 SEP 2020 14:38

PC Close Date & Time

05 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 2

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 19:00

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

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

06 SEP 2020 18:52

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

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

07 SEP 2020 19:00

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

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

08 SEP 2020 19:04

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

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

09 SEP 2020 19:40

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

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

10 SEP 2020 19:09

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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 ☐

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 11:53
PC Open Date & Time	04 SEP 2020 11:13
PC Close Date & Time	04 SEP 2020 13:43

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

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 ☐

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 14:41
PC Open Date & Time	04 SEP 2020 14:38
PC Close Date & Time	05 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

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)

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US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

Yes ☐	
PC Time stamp	05 SEP 2020 19:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

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

57 of 2508

EAB) (1725)

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

Yes ☐	
PC Time stamp	06 SEP 2020 18:52
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

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 ☒

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

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

61 of 2508

EAB) (1725)

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

Yes ☐	
PC Time stamp	08 SEP 2020 19:04
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

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

63 of 2508

EAB) (1725)

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

Yes ☐	
PC Time stamp	09 SEP 2020 19:40
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

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 ☒

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

Yes ☐	
PC Time stamp	10 SEP 2020 19:10
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3952004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952004

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952004

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952004

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	06 OCT 2020

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

Folder OID	VISIT2

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	08:31 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 08:31
Temperature (xxx.x)	37.0 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 10:15
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3952004

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

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.

US3952004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

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) 06 OCT 2020

What was the treatment time? (00:00-23:59) 09:35 (24 HR)

Treatment Date and Time (derived) 06 OCT 2020 09:35

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

US3952004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	06 OCT 2020
Collection time (00:00-23:59)	09:07 (24 HR)
Collection date and time (derived)	06 OCT 2020 09:07

US3952004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Collection date (dd MMM yyyy)			06 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:09	06 OCT 2020 09:09
Nasopharyngeal Swab 2	No		

US3952004

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 10:21

PC Open Date & Time

06 OCT 2020 09:55

PC Close Date & Time

06 OCT 2020 12:25

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	06 OCT 2020 15:53
PC Open Date & Time	06 OCT 2020 13:20
PC Close Date & Time	07 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

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

100.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 12:02

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

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

98.2 °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

08 OCT 2020 17:23

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 13:09

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 19:24

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 12:02

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

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.

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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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 12:02

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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

06 OCT 2020 10:13

PC Open Date & Time

06 OCT 2020 09:55

PC Close Date & Time

06 OCT 2020 12:25

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 15:53

PC Open Date & Time

06 OCT 2020 13:20

PC Close Date & Time

07 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 12:03

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

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

08 OCT 2020 17:23

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

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

09 OCT 2020 13:10

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

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

10 OCT 2020 19:24

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

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

11 OCT 2020 12:02

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

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

12 OCT 2020 12:03

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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 ☐

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 10:13
PC Open Date & Time	06 OCT 2020 09:55
PC Close Date & Time	06 OCT 2020 12:25

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

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 ☐

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 15:54
PC Open Date & Time	06 OCT 2020 13:20
PC Close Date & Time	07 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

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)

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US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

Yes ☐	
PC Time stamp	07 OCT 2020 12:04
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

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

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EAB) (1725)

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

Yes ☐	
PC Time stamp	08 OCT 2020 17:23
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

Yes ☐	
PC Time stamp	09 OCT 2020 13:10
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

Yes ☐	
PC Time stamp	10 OCT 2020 19:25
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

Yes ☐	
PC Time stamp	11 OCT 2020 12:02
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

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)

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US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

Yes ☐	
PC Time stamp	12 OCT 2020 12:03
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3952004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952004

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952004

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952004

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	03 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	03 NOV 2020
Time of assessment (00:00-23:59)	08:14 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 08:14
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952004

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

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.

US3952004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	03 NOV 2020
Collection time (00:00-23:59)	08:17 (24 HR)
Collection date and time (derived)	03 NOV 2020 08:17

US3952004

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 18:29:37

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 NOV 2020 12:00:22

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 07:34:36

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 75

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

No ☒

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

19 NOV 2020 18:39:38

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 14:31:02
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 19:37:10
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

Date and time of submission

07 DEC 2020 18:37:44

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 20:27:30

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 00:02:13

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

27 DEC 2020 01:44:08

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

03 JAN 2021 00:02:50

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

10 JAN 2021 00:02:00

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

19 JAN 2021 12:17:21

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 08:25:25

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 FEB 2021 12:09:11

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 12:03:27

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 18:50:35
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 00:07:33

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 05:12:09

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 00:03:02

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 00:02:50

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 18:39:50

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 13:42:52

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 13:47:12

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 10:34:20

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 08:00:25

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 00:03:03

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 08:22:20

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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 ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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 ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 446

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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 ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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 ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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12 MAY 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 656

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

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

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

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

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

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

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 ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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 ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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 ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 768

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

DAY 796

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

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3952004

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:32:34

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 05:12:31

US3952004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:35:09

Generated On: 10 Jun 2021 10:32:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952004

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952004

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952004

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT4

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 MAR 2021
Time of assessment (00:00-23:59)	08:48 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 08:48
Temperature (xxx.x)	37.2 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952004

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

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.

US3952004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

09:06 (24 HR)

Collection date and time (derived)

23 MAR 2021 09:06

US3952004

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:22:32

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952004

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

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

US3952004

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3952004

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:32:34

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
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 ☐

US3952004

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:32:34

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3952004

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

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	04 FEB 2021

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

Folder OID	UNBLND_DECIDE

US3952004

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

Form: Unblinding

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Date of updated informed consent (dd MMM yyyy) 04 FEB 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 (dd MMM yyyy) 04 FEB 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 _____
Continuing with mRNA-1273 _____

US3952004

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	04 FEB 2021
Collection time (00:00-23:59)	14:45 (24 HR)
Collection date and time (derived)	04 FEB 2021 14:45

US3952004

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	04 FEB 2021
Collection time (00:00 - 23:59)	14:48
Collection Date and Time (derived)	04 FEB 2021 14:48

US3952004

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Feb 2021 18:06:21

Generated On: 10 Jun 2021 10:32:34

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:20:18

Generated On: 10 Jun 2021 10:32:34

AEID	USA-US215-2021-MRNA-1273-P30 1000002
Adverse event	WORSENING OF DEGENERATIVE SPONDYLOLITHESIS
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)	22 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	24 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	24 DEC 2020
Admitted to ICU?	Yes ☐ No ☒
PRODUCTION RELEASE (v12.003 EAB) (1725)	333 of 2508

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:20:18

Generated On: 10 Jun 2021 10:32:34

	Unknown	☐
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		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		

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:20:18

Generated On: 10 Jun 2021 10:32:34

SUBJECT HAS HX OF
WORSENING DEGENERATIVE
SPONDYLOLISTHESIS,
INITIALLY DIAGNOSED IN 2010.
SHE WAS ADMITTED TO
HOSPITAL ON 22DEC2020 FOR
A LUMBAR SPINAL FUSION.
HAD AN UNEVENTFUL COURSE
AND WAS DISCHARGED ON
24DEC2020.

FURTHER DETAILS WILL BE
PROVIDED UPON RECEIPT OF
MEDICAL RECORDS.

HOSPITAL RECORDS RECEIVED
AND COURSE OF
HOSPITALIZATION IS
OUTLINED. SUBJECT WAS
ADMITTED FOR ELECTIVE
L4-L5 LAMINECTOMY AND
FUSION. SHE UNDERWENT
GENERAL ANESTHESIA AND
SURGERY WAS PERFORMED
WITHOUT COMPLICATION.

SUBJECT RECEIVED
PERI-OPERATIVE ANCEF UNTIL
POST OP DAY 2 WHEN
SURGICAL DRAIN WAS
REMOVED. MECHANICAL DVT
PROPHYLAXIS WITH TED
STOCKS AND SCDS WERE
USED. ON DAY OF DISCHARGE
SUBJECT WAS DOING WELL
WITH PAIN CONTROLLED ON

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:20:18

Generated On: 10 Jun 2021 10:32:34

AN ORAL REGIMEN. SHE WAS
EVALUATED BY PT AND
CLEARED FOR DISCHARGE TO
HOME ON 24DEC2020.

SUBJECT WAS SEEN IN
RESEARCH SITE FOR VISIT
LAST WEEK AND NOTED TO BE
DOING VERY WELL.

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

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

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

Yes ☒

No ☐

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

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 2015	
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	☒

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 2010	
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	☒

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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	2015
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication DICLOFENAC

Prophylaxis Yes ☐
No ☒

Indication HERNIATED LUMBAR DISKS

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	16 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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication STEROID INJECTION

Prophylaxis Yes ☐
No ☒

Indication HERNIATED LUMBAR DISKS

Dose per administration 1

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

If dose unit is Other, specify DOSE

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 TWO MONTHS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	SPINAL	
Start date (dd MMM yyyy)	12 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication ACETYLSALICYCLIC ACID

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 2015
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	☒

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	19 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	☒

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication BETOPTIC 0.25%

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP PER EYE

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 2000	
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	☒

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication DYMISTA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 137-50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 2015	
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	☒

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication ESCITALOPRAM OXALATE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 2017
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication ROSACEA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)		04 SEP 2020
Start date completely unknown		False
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 22 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 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication SULFACETAMIDE WASH

Prophylaxis Yes ☐
No ☒

Indication ROSACEA

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)		04 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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication ELIDEL 1%

Prophylaxis Yes ☐
No ☒

Indication ROSACEA

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)		04 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication METRONIDAZOLE 0.75%

Prophylaxis Yes ☐
No ☒

Indication ROSACEA

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)		04 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Apr 2021 20:21:11

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	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		26 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)		19 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication HYDROCODONE

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 02 JAN 2021		
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication TYLENOL ES

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		02 JAN 2021
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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	22 DEC 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 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	22 DEC 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 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

Dose per administration 1000

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☒
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 24 DEC 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	☒

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication CEFAZOLIN (ANCEF)

Prophylaxis Yes ☒
No ☐

Indication POST-OP PROPHYLAXIS

Dose per administration 2/100

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify G/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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 22 DEC 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy) 22 DEC 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 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		23 DEC 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	☐

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)		22 FEB 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		24 DEC 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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication GENTAMYCIN

Prophylaxis Yes ☒
No ☐

Indication POST-OP PROPHYLAXIS

Dose per administration 80/100

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 22 DEC 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication HYDROMORPHAN (DILAUDID)

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

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

EVERY TEN MINUTES AS
NEEDED

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		22 DEC 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	☐

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication POST-OP FLUIDS

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

CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)		22 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 23 DEC 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	☐

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

Dose per administration 2/50

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify G/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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)		22 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 22 DEC 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication ONDANSETRON (ZOFTRAN)

Prophylaxis Yes ☐
No ☒

Indication POST-OP 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	23 DEC 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 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 22 DEC 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication SENNOSIDES

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 17.2

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 23 DEC 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	☒

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication TRANEXAMIC ACID (TCX)

Prophylaxis Yes ☒
No ☐

Indication POST-OP BLEEDING

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	22 DEC 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 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication BETOXALOL 0.5%

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 24 DEC 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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication POST OP PAIN

Dose per administration 300

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 15 Apr 2021 20:21:11

Generated On: 10 Jun 2021 10:32:34

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 22 DEC 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	☒

US3952004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3952004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 DEC 2020	LUMBAR FUSION; LUMBAR LAMINECTOMY	Adverse Event	
22 DEC 2020	XR L SPINE 1 VW	Other	INTRAOPERATIVE IMAGING

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:32:34

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3952004

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:32:34

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

SAEID	USA-US215-2021-MRNA-1273-P301000002
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)	4

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

SAEID	USA-US215-2021-MRNA-1273-P301000002
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)	4
Date of submission (Pre-filled from custom function)	09/FEB/2021 13:13
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

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

SAEID	USA-US215-2021-MRNA-1273-P301000002
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)	4
Date of submission (Pre-filled from custom function)	05/MAR/2021 12:48
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

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

SAEID	USA-US215-2021-MRNA-1273-P301000002
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)	4
Date of submission (Pre-filled from custom function)	15/MAR/2021 09:20
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

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 07 Apr 2021 21:35:07

Generated On: 10 Jun 2021 10:32:34

SAEID	USA-US215-2021-MRNA-1273-P301000002
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)	4
Date of submission (Pre-filled from custom function)	26/MAR/2021 10:50
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

Audit

US3952004 (Prod: Synexus - Optimal Research - Rockville)

US3952004

Form: Participant Creation

Generated On: 10 Jun 2021 10:32:34

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 17:16:25
User entered 'US3952004'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:05:50

US3952004

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:22:55
User closed query 'Per CDM: please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 06:10:44
Query 'Per CDM: please complete all applicable forms for this visit.' answered with 'updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:03:14
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:03:08
User opened query 'Per CDM: please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	30 Aug 2020 23:58:21

US3952004

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:22:57
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:05:51

US3952004

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:23:01
User entered 'Clinic (Clinic)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:03:08

US3952004

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'SCRN'	System	03 Sep 2020 17:03:08

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:26:27
User entered (b) (6) 1951'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:05:52

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:26:30
User entered '69'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'YEARS'	System	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '69'	System	03 Sep 2020 17:05:23

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:27:10
User entered 'Female (F)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:27:12
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:27:17
User entered '1'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:27:26
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:27:28
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:27:30
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:27:31
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:27:34
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:27:36
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:27:39
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:32:34

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:27:41
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:04:54

US3952004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:32:34

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:28:09
User entered '28 Aug 2020'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:05:23

US3952004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:32:34

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Aug 2020'	System	03 Sep 2020 17:05:23

US3952004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:32:34

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2020'	System	03 Sep 2020 17:05:23

US3952004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:32:34

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:28:12
User entered 'Amendment 3 (3)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:05:23

US3952004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:32:34

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:28:14
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:05:23

US3952004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:32:34

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:28:24
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:05:23

US3952004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:32:34

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:28:26
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:05:23

US3952004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:32:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:28:28
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:05:23

US3952004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:32:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:28:30
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:05:51

US3952004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:32:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '1'	System	03 Sep 2020 17:06:50

US3952004

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:32:34

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:31:04
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:06:50

US3952004

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:32:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:34:29
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:10:08

US3952004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:34:56
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:12:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:12:43
Data point term sent to Coder	System	03 Sep 2020 17:11:17
User entered 'hypertension'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:10:31

US3952004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:34:58
User entered 'un UNK 2015'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:10:31

US3952004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:01
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:10:31

US3952004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:15
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:10:31

US3952004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:32:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:18
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:10:31

US3952004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:21
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:10:31

US3952004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2015'	System	03 Sep 2020 17:10:31

US3952004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2015'	System	03 Sep 2020 17:10:31

US3952004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:10:31

US3952004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:10:31

US3952004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:12:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:12:45
Data point term sent to Coder	System	03 Sep 2020 17:12:19
User entered 'glaucoma'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:11:52

US3952004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:32:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'un UNK 2000'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:11:52

US3952004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:32:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:11:52

US3952004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:11:52

US3952004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:32:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:11:52

US3952004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:11:52

US3952004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2000'	System	03 Sep 2020 17:11:52

US3952004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2000'	System	03 Sep 2020 17:11:52

US3952004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:11:52

US3952004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:11:52

US3952004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:12:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:12:44
Data point term sent to Coder	System	03 Sep 2020 17:12:20
User entered 'seasonal allergies'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:08

US3952004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:32:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'un UNK 1956'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:08

US3952004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:32:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:08

US3952004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:08

US3952004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:32:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:08

US3952004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:08

US3952004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 1956'	System	03 Sep 2020 17:12:08

US3952004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '1956'	System	03 Sep 2020 17:12:08

US3952004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:12:08

US3952004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:12:08

US3952004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
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)	03 Sep 2020 17:13:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:13:41
Data point term sent to Coder	System	03 Sep 2020 17:13:23
User entered 'depression'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:23

US3952004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:32:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'un UNK 2017'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:23

US3952004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:32:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:23

US3952004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:23

US3952004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:32:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:23

US3952004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:23

US3952004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2017'	System	03 Sep 2020 17:12:23

US3952004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2017'	System	03 Sep 2020 17:12:23

US3952004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:12:23

US3952004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:12:23

US3952004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:13:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:13:40
Data point term sent to Coder	System	03 Sep 2020 17:13:21
User entered 'gerd'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:36

US3952004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:32:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'un UNK 2010'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:36

US3952004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:32:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:36

US3952004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:36

US3952004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:32:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:36

US3952004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:36

US3952004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2010'	System	03 Sep 2020 17:12:36

US3952004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2010'	System	03 Sep 2020 17:12:36

US3952004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:12:36

US3952004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:12:36

US3952004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 20:06:50
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:13:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:13:40
Data point term sent to Coder	System	03 Sep 2020 17:13:23
User entered 'hyperlipidemia'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:51

US3952004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'un UNK 2015'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:51

US3952004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:32:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:51

US3952004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:51

US3952004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:32:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:51

US3952004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:12:51

US3952004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2015'	System	03 Sep 2020 17:12:51

US3952004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2015'	System	03 Sep 2020 17:12:51

US3952004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:12:51

US3952004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:12:51

US3952004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Lumbar disc herniation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 23:10:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 23:10:48
Data point term sent to Coder	System	03 Sep 2020 17:13:23
User entered 'herniated lumbar disks'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:13

US3952004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:32:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'un UNK 2010'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:13

US3952004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:32:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:13

US3952004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:13

US3952004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:32:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:13

US3952004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:13

US3952004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2010'	System	03 Sep 2020 17:13:13

US3952004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2010'	System	03 Sep 2020 17:13:13

US3952004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:13:13

US3952004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:13:13

US3952004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:15:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:15:48
Data point term sent to Coder	System	03 Sep 2020 17:14:24
User entered 'osteoarthritis'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:26

US3952004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:32:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'un UNK 2010'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:26

US3952004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:26

US3952004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:26

US3952004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:32:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:26

US3952004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:26

US3952004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2010'	System	03 Sep 2020 17:13:26

US3952004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2010'	System	03 Sep 2020 17:13:26

US3952004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:13:26

US3952004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	03 Sep 2020 17:13:26

US3952004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User closed query 'Per DM CLR: Please note, stop date of MH = UN UNK 2015. However, no procedure or treatment recorded for this condition. Review and update medical history as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 08:48:18
Query 'Per DM CLR: Please note, stop date of MH = UN UNK 2015. However, no procedure or treatment recorded for this condition. Review and update medical history as appropriate. Else, clarify. ' answered with 'MH updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:55:26
User opened query 'Per DM CLR: Please note, stop date of MH = UN UNK 2015. However, no procedure or treatment recorded for this condition. Review and update medical history as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:00:52
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Right cataract - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:15:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:15:49
Data point term sent to Coder	System	03 Sep 2020 17:14:25

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
User entered 'right eye cataract'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:48

US3952004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'un UNK 2015'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:48

US3952004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:32:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:48

US3952004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:48

US3952004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:32:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered 'un UNK 2015'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:48

US3952004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:38:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:38:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:37:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 16:36:14
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:35:47
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:13:48

US3952004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2015'	System	03 Sep 2020 17:13:48

US3952004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2015'	System	03 Sep 2020 17:13:48

US3952004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2015'	System	03 Sep 2020 17:13:48

US3952004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2015'	System	03 Sep 2020 17:13:48

US3952004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 14:44:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 14:44:03
Data point term sent to Coder	System	14 Dec 2020 14:42:19
User entered 'ROSACEA'	(b) (4), (b) (6)	14 Dec 2020 14:42:13

US3952004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered 'UN UNK 2018'	(b) (4), (b) (6)	14 Dec 2020 14:42:13

US3952004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 14:42:13

US3952004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	14 Dec 2020 14:42:45
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	14 Dec 2020 14:42:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 14:42:13

US3952004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:32:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 14:42:13

US3952004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 14:42:45
User entered '1'	(b) (4), (b) (6)	14 Dec 2020 14:42:13

US3952004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2018'	System	14 Dec 2020 14:42:13

US3952004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2018'	System	14 Dec 2020 14:42:13

US3952004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	14 Dec 2020 14:42:13

US3952004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	14 Dec 2020 14:42:13

US3952004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spondylolisthesis, LLT: Spondylolisthesis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 15:54:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 15:54:30
Data point term sent to Coder	System	14 Dec 2020 14:47:29
User entered 'DEGENERATIVE SPONDYLOLISTHESIS'	(b) (4), (b) (6)	14 Dec 2020 14:47:21

US3952004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered 'UN UNK 2010'	(b) (4), (b) (6)	14 Dec 2020 14:47:21

US3952004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 14:47:21

US3952004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:42:02
User closed query 'Per updated Med Hx, subject's condition is no longer on-going.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 15:41:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per updated Med Hx, subject's condition is no longer on-going.' answered with 'Line is called "Condition ongoing at study entry". Does the line have to be changed to "no" even though the Med Hx. was ongoing at study entry?' (Site from CRA).	Atanas Filev (b) (4)	08 Apr 2021 00:13:11
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:53:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:53:05
User opened query 'Per updated Med Hx, subject's condition is no longer on-going.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:53:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 14:47:21

US3952004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:32:34

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 14:47:21

US3952004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 14:47:21

US3952004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2010'	System	14 Dec 2020 14:47:21

US3952004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2010'	System	14 Dec 2020 14:47:21

US3952004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	14 Dec 2020 14:47:21

US3952004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	14 Dec 2020 14:47:21

US3952004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:17
Data point term sent to Coder	System	21 Dec 2020 14:56:56
User entered 'right eye cataract surgery'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:56:21

US3952004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered 'un UNK 2015'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:56:21

US3952004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered '0'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:56:21

US3952004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:56:21

US3952004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:32:34

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered 'un UNK 2015'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:56:21

US3952004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered '0'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:56:21

US3952004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2015'	System	21 Dec 2020 14:56:21

US3952004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2015'	System	21 Dec 2020 14:56:21

US3952004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 2015'	System	21 Dec 2020 14:56:21

US3952004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '2015'	System	21 Dec 2020 14:56:21

US3952004

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:32:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:17
Data point term sent to Coder	System	21 Dec 2020 14:56:56
User entered 'menopause'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:56:29

US3952004

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered 'un UNK 1990'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:56:29

US3952004

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered '0'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:56:29

US3952004

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:32:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:56:29

US3952004

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:32:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:56:29

US3952004

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:32:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:53:05
User entered '0'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:56:29

US3952004

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:32:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'Jan 1990'	System	21 Dec 2020 14:56:29

US3952004

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:32:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '1990'	System	21 Dec 2020 14:56:29

US3952004

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:32:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	21 Dec 2020 14:56:29

US3952004

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:32:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	21 Dec 2020 14:56:29

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:33
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:33
User entered '28 Aug 2020'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:33
User entered '11:11'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '28 Aug 2020 11:11'	System	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:33
User entered '63.0' in	Nick Bart (b) (4)	03 Sep 2020 17:09:53
DataPoint set to visible.	(b) (4) System	03 Sep 2020 17:06:50

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:33
User entered '168.0' lb	Nick Bart (b) (4)	03 Sep 2020 17:09:53
DataPoint set to visible.	(b) (4) System	03 Sep 2020 17:06:50

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '29.82209'	System	03 Sep 2020 17:09:53
DataPoint set to visible.	System	03 Sep 2020 17:06:50

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'kg/m2'	System	03 Sep 2020 17:09:53
DataPoint set to visible.	System	03 Sep 2020 17:06:50

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:02:36
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Nick Bart (b) (4) (b) (4)	25 Sep 2020 17:48:44
answered with 'NCS' (Site from System).		
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:09:24
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:41:33
User entered '35.9' C	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:33
User entered 'Oral (Oral)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:33
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:33
User entered '60'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'bpm'	System	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:33
User entered '14'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'breaths/min'	System	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:33
User entered '139'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'mmHg'	System	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:33
User entered '82'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'mmHg'	System	03 Sep 2020 17:09:53

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00

US3952004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00

US3952004

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:32:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:56
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:14:05

US3952004

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:32:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:58
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 12:17:26
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		04 Sep 2020 15:42:10
User entered '28 Aug 2020'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:14:05

US3952004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:32:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:43:12
User entered '28 Aug 2020'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:08:38

US3952004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:32:34

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:43:12
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:08:38

US3952004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:32:34

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:20:52
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'MH updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:55:12
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:49:22
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:43:12
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:08:38

US3952004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:32:34

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:43:12
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:08:38

US3952004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:32:34

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:43:12
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:08:38

US3952004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:32:34

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:43:12
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:08:38

US3952004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:32:34

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:43:12
User entered 'un UNK 1990'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:08:38

US3952004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:32:34

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:43:12
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:08:38

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
User entered '1'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered '0'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
User entered '0'	(b) (4)	03 Sep 2020 17:07:32
	Nick Bart (b) (4)	
	(b) (4)	

US3952004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:32:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:34
User entered empty.	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:07:32

US3952004

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:21:44
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:15:02

US3952004

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:21:44
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	04 Sep 2020 15:42:10
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered by data change (Site from System).	System	04 Sep 2020 15:42:10
User entered '04 Sep 2020' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	04 Sep 2020 15:42:10
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	04 Sep 2020 15:20:55
User entered '28 Aug 2020'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:15:02

US3952004

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:21:44
User entered 'Clinic (Clinic)'	Nick Bart (b) (4) (b) (4)	03 Sep 2020 17:15:02

US3952004

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'VISIT1'	System	03 Sep 2020 17:15:02

US3952004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:32:34

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:24:25
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 15:42:10
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	04 Sep 2020 15:42:10
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 14:14:16
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:14:16

US3952004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:32:34

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:24:25
User entered '189574'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:14:16

US3952004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:32:34

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:24:25
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:14:16

US3952004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:32:34

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)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:24:25
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:50:15

US3952004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:32:34

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)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:24:25
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:50:15

US3952004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:32:34

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:24:25
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:50:15

US3952004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:32:34

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:24:25
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:50:15

US3952004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:32:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:24:25
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:50:15

US3952004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:32:34

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:24:25
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	25 Sep 2020 12:49:12
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:25:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:25:56

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:32:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:32:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:32:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:32:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '04 Sep 2020'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '09:09'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '04 Sep 2020 09:09'	System	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '36.8' C	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered 'Oral (Oral)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '75'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'bpm'	System	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '14'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'breaths/min'	System	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '124'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'mmHg'	System	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '77'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'mmHg'	System	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:32:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:32:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '04 Sep 2020'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '11:47'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '04 Sep 2020 11:47'	System	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '36.8' C	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered 'Oral (Oral)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '63'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'bpm'	System	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '14'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'breaths/min'	System	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '122'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'mmHg'	System	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:40
User entered '77'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'mmHg'	System	09 Sep 2020 20:52:33

US3952004

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:32:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:46
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:45

US3952004

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:32:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:28:46
User entered '04 Sep 2020'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:52:45

US3952004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:36:37
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	04 Sep 2020 15:20:55

US3952004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:36:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	04 Sep 2020 15:20:55

US3952004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:36:37
User entered empty.	Atanas Filev (b) (4) (b) (4)	04 Sep 2020 15:20:55

US3952004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 15:20:55

US3952004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:36:37
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 15:42:10
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	04 Sep 2020 15:42:10
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 15:20:55
User entered '04 Sep 2020'	Atanas Filev (b) (4) (b) (4)	04 Sep 2020 15:20:55

US3952004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:36:37
User entered '10:53'	Atanas Filev (b) (4) (b) (4)	04 Sep 2020 15:20:55

US3952004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '04 Sep 2020 10:53'	System	04 Sep 2020 15:20:55

US3952004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:36:37
User entered 'Left Arm (LEFT ARM)'	Atanas Filev (b) (4) (b) (4)	04 Sep 2020 15:20:55

US3952004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:36:37
User entered 'ONCE'	System	04 Sep 2020 15:20:55

US3952004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 15:20:55

US3952004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:36:58
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:53:23

US3952004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:36:58
User entered '04 Sep 2020'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:53:23

US3952004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:36:58
User entered '09:50'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:53:23

US3952004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '04 Sep 2020 09:50'	System	09 Sep 2020 20:53:23

US3952004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:32:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:37:15
User entered '04 Sep 2020'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:53:54

US3952004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:32:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:53:54

US3952004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:32:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:37:15
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:53:54

US3952004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:32:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:37:15
User entered '09:55'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:53:54

US3952004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:32:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '04 Sep 2020 09:55'	System	09 Sep 2020 20:53:54

US3952004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:32:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:53:54

US3952004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:32:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:37:15
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:53:54

US3952004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:32:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:37:15
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:53:54

US3952004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:32:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered empty.	System	09 Sep 2020 20:53:54

US3952004

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:38:03
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:53:07

US3952004

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '1'	System	09 Sep 2020 20:53:07

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:49:54', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b797ca0f-ae6b-4b80-be11-5cf34a4e83d7'	System	04 Sep 2020 15:50:21
User entered 'Yes (Y)'	System	04 Sep 2020 15:50:21

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:50:01', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b797ca0f-ae6b-4b80-be11-5cf34a4e83d7' User entered '98.2'	System	04 Sep 2020 15:50:21
	System	04 Sep 2020 15:50:21

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:50:08', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b797ca0f-ae6b-4b80-be11-5cf34a4e83d7'	System	04 Sep 2020 15:50:21
User entered 'No (N)'	System	04 Sep 2020 15:50:21

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:50:19', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b797ca0f-ae6b-4b80-be11-5cf34a4e83d7'	System	04 Sep 2020 15:50:21
User entered '04 Sep 2020 11:50'	System	04 Sep 2020 15:50:21

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '04 Sep 2020 11:13'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '04 Sep 2020 13:43'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:40:25', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '74516521-4bd2-48e2-a16d-21b83a7f21ea' User entered 'Yes (Y)'	System	04 Sep 2020 18:40:53
	System	04 Sep 2020 18:40:53

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:40:33', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '74516521-4bd2-48e2-a16d-21b83a7f21ea' User entered '97.7'	System	04 Sep 2020 18:40:53
	System	04 Sep 2020 18:40:53

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:40:38', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '74516521-4bd2-48e2-a16d-21b83a7f21ea' User entered 'No (N)'	System	04 Sep 2020 18:40:53
	System	04 Sep 2020 18:40:53

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:40:50', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '74516521-4bd2-48e2-a16d-21b83a7f21ea' User entered '04 Sep 2020 14:40'	System	04 Sep 2020 18:40:53
	System	04 Sep 2020 18:40:53

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '04 Sep 2020 14:38'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 2'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T18:58:35', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd541fb4e-2cef-4358-b5ee-7300f1ddf040' User entered 'Yes (Y)'	System	05 Sep 2020 22:58:59
	System	05 Sep 2020 22:58:59

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T18:58:46', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd541fb4e-2cef-4358-b5ee-7300f1ddf040' User entered '99.7'	System	05 Sep 2020 22:58:59
	System	05 Sep 2020 22:58:59

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T18:58:51', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd541fb4e-2cef-4358-b5ee-7300f1ddf040'	System	05 Sep 2020 22:58:59
User entered 'No (N)'	System	05 Sep 2020 22:58:59

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T18:58:57', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd541fb4e-2cef-4358-b5ee-7300f1ddf040'	System	05 Sep 2020 22:58:59
User entered '05 Sep 2020 18:58'	System	05 Sep 2020 22:58:59

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 3'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:51:36', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9ea6847a-2064-4fc6-ab6a-6dc5da844c3a' User entered 'Yes (Y)'	System	06 Sep 2020 22:51:59
	System	06 Sep 2020 22:51:59

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:51:46', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9ea6847a-2064-4fc6-ab6a-6dc5da844c3a' User entered '98.5'	System	06 Sep 2020 22:51:59
	System	06 Sep 2020 22:51:59

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:51:51', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9ea6847a-2064-4fc6-ab6a-6dc5da844c3a' User entered 'No (N)'	System	06 Sep 2020 22:51:59
	System	06 Sep 2020 22:51:59

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:51:56', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9ea6847a-2064-4fc6-ab6a-6dc5da844c3a' User entered '06 Sep 2020 18:51'	System	06 Sep 2020 22:51:59
	System	06 Sep 2020 22:51:59

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 4'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T18:59:06', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'a7af73e8-b5f8-44bc-842b-ba44b4b8160d' User entered 'Yes (Y)'	System	07 Sep 2020 22:59:50
	System	07 Sep 2020 22:59:50

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T18:59:36', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'a7af73e8-b5f8-44bc-842b-ba44b4b8160d' User entered '99.1'	System	07 Sep 2020 22:59:50
	System	07 Sep 2020 22:59:50

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T18:59:41', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'a7af73e8-b5f8-44bc-842b-ba44b4b8160d' User entered 'No (N)'	System	07 Sep 2020 22:59:50
	System	07 Sep 2020 22:59:50

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T18:59:48', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'a7af73e8-b5f8-44bc-842b-ba44b4b8160d' User entered '07 Sep 2020 18:59'	System	07 Sep 2020 22:59:50
	System	07 Sep 2020 22:59:50

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 5'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:03:35', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '6074213e-d658-49ae-a1f8-133890810593' User entered 'Yes (Y)'	System	08 Sep 2020 23:03:54
	System	08 Sep 2020 23:03:54

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:03:46', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '6074213e-d658-49ae-a1f8-133890810593' User entered '98.6'	System	08 Sep 2020 23:03:54
	System	08 Sep 2020 23:03:54

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:03:25', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '6074213e-d658-49ae-a1f8-133890810593' User entered 'No (N)'	System	08 Sep 2020 23:03:54
	System	08 Sep 2020 23:03:54

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:03:52', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '6074213e-d658-49ae-a1f8-133890810593' User entered '08 Sep 2020 19:03'	System	08 Sep 2020 23:03:54
	System	08 Sep 2020 23:03:54

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 6'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:39:34', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f6cb2665-5b76-4033-bd4f-e469b4d30a00' User entered 'Yes (Y)'	System	09 Sep 2020 23:39:51
	System	09 Sep 2020 23:39:51

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:39:42', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f6cb2665-5b76-4033-bd4f-e469b4d30a00' User entered '98.0'	System	09 Sep 2020 23:39:51
	System	09 Sep 2020 23:39:51

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:39:45', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f6cb2665-5b76-4033-bd4f-e469b4d30a00' User entered 'No (N)'	System	09 Sep 2020 23:39:51
	System	09 Sep 2020 23:39:51

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:39:50', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f6cb2665-5b76-4033-bd4f-e469b4d30a00' User entered '09 Sep 2020 19:39'	System	09 Sep 2020 23:39:51
	System	09 Sep 2020 23:39:51

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 7'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:10', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '1fa30c50-9353-4f92-b8f9-5335aa879f4b' User entered 'Yes (Y)'	System	10 Sep 2020 23:09:25
	System	10 Sep 2020 23:09:25

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:16', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '1fa30c50-9353-4f92-b8f9-5335aa879f4b' User entered '98.5'	System	10 Sep 2020 23:09:25
	System	10 Sep 2020 23:09:25

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:20', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '1fa30c50-9353-4f92-b8f9-5335aa879f4b' User entered 'No (N)'	System	10 Sep 2020 23:09:25
	System	10 Sep 2020 23:09:25

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:24', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '1fa30c50-9353-4f92-b8f9-5335aa879f4b' User entered '10 Sep 2020 19:09'	System	10 Sep 2020 23:09:25
	System	10 Sep 2020 23:09:25

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:51:31', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7b8effc1-4970-47e8-b961-704761369816'	System	04 Sep 2020 15:53:09
User entered 'None (1)'	System	04 Sep 2020 15:53:09

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:51:35', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7b8effc1-4970-47e8-b961-704761369816' User entered 'No (N)'	System	04 Sep 2020 15:53:09
	System	04 Sep 2020 15:53:09

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:52:23', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7b8effc1-4970-47e8-b961-704761369816' User entered 'No (N)'	System	04 Sep 2020 15:53:09
	System	04 Sep 2020 15:53:09

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:52:55', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7b8effc1-4970-47e8-b961-704761369816' User entered 'None (1)'	System	04 Sep 2020 15:53:09
	System	04 Sep 2020 15:53:09

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:53:06', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7b8effc1-4970-47e8-b961-704761369816' User entered '04 Sep 2020 11:53'	System	04 Sep 2020 15:53:09
	System	04 Sep 2020 15:53:09

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '04 Sep 2020 11:13'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '04 Sep 2020 13:43'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:01', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd9e5b934-6026-4947-be8d-344109e0378a' User entered 'None (1)'	System	04 Sep 2020 18:41:19
	System	04 Sep 2020 18:41:19

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:05', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd9e5b934-6026-4947-be8d-344109e0378a' User entered 'No (N)'	System	04 Sep 2020 18:41:19
	System	04 Sep 2020 18:41:19

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:08', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd9e5b934-6026-4947-be8d-344109e0378a' User entered 'No (N)'	System	04 Sep 2020 18:41:19
	System	04 Sep 2020 18:41:19

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:11', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd9e5b934-6026-4947-be8d-344109e0378a'	System	04 Sep 2020 18:41:19
User entered 'None (1)'	System	04 Sep 2020 18:41:19

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:17', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd9e5b934-6026-4947-be8d-344109e0378a' User entered '04 Sep 2020 14:41'	System	04 Sep 2020 18:41:19
	System	04 Sep 2020 18:41:19

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '04 Sep 2020 14:38'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 2'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T18:59:14', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd7d19526-ab68-471f-bc16-e680b8adb34f' User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 23:00:39
	System	05 Sep 2020 23:00:39

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T18:59:18', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd7d19526-ab68-471f-bc16-e680b8adb34f' User entered 'No (N)'	System	05 Sep 2020 23:00:39
	System	05 Sep 2020 23:00:39

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T19:00:05', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd7d19526-ab68-471f-bc16-e680b8adb34f' User entered 'No (N)'	System	05 Sep 2020 23:00:39
	System	05 Sep 2020 23:00:39

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T19:00:16', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd7d19526-ab68-471f-bc16-e680b8adb34f' User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 23:00:39
	System	05 Sep 2020 23:00:39

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T19:00:37', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd7d19526-ab68-471f-bc16-e680b8adb34f' User entered '05 Sep 2020 19:00'	System	05 Sep 2020 23:00:39
	System	05 Sep 2020 23:00:39

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 3'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:06', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5226140c-1f87-4f2f-9e2d-3c6ab0d14f93'	System	06 Sep 2020 22:52:24
User entered 'None (1)'	System	06 Sep 2020 22:52:24

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:09', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5226140c-1f87-4f2f-9e2d-3c6ab0d14f93'	System	06 Sep 2020 22:52:24
User entered 'No (N)'	System	06 Sep 2020 22:52:24

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:12', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5226140c-1f87-4f2f-9e2d-3c6ab0d14f93' User entered 'No (N)'	System	06 Sep 2020 22:52:24
	System	06 Sep 2020 22:52:24

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:15', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5226140c-1f87-4f2f-9e2d-3c6ab0d14f93'	System	06 Sep 2020 22:52:24
User entered 'None (1)'	System	06 Sep 2020 22:52:24

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:21', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5226140c-1f87-4f2f-9e2d-3c6ab0d14f93' User entered '06 Sep 2020 18:52'	System	06 Sep 2020 22:52:24
	System	06 Sep 2020 22:52:24

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 4'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T18:59:53', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ca143c1b-9f17-4c84-86a8-1b1aa2fb2d36'	System	07 Sep 2020 23:00:14
User entered 'None (1)'	System	07 Sep 2020 23:00:14

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T18:59:58', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ca143c1b-9f17-4c84-86a8-1b1aa2fb2d36'	System	07 Sep 2020 23:00:14
User entered 'No (N)'	System	07 Sep 2020 23:00:14

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T19:00:02', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ca143c1b-9f17-4c84-86a8-1b1aa2fb2d36'	System	07 Sep 2020 23:00:14
User entered 'No (N)'	System	07 Sep 2020 23:00:14

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T19:00:06', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ca143c1b-9f17-4c84-86a8-1b1aa2fb2d36'	System	07 Sep 2020 23:00:14
User entered 'None (1)'	System	07 Sep 2020 23:00:14

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T19:00:10', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ca143c1b-9f17-4c84-86a8-1b1aa2fb2d36'	System	07 Sep 2020 23:00:14
User entered '07 Sep 2020 19:00'	System	07 Sep 2020 23:00:14

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 5'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:03:56', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '02f0ba23-dc2a-492b-8e73-4e7b18ac113f' User entered 'None (1)'	System	08 Sep 2020 23:04:12
	System	08 Sep 2020 23:04:12

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:03:59', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '02f0ba23-dc2a-492b-8e73-4e7b18ac113f' User entered 'No (N)'	System	08 Sep 2020 23:04:12
	System	08 Sep 2020 23:04:12

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:04:01', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '02f0ba23-dc2a-492b-8e73-4e7b18ac113f' User entered 'No (N)'	System	08 Sep 2020 23:04:12
	System	08 Sep 2020 23:04:12

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:04:04', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '02f0ba23-dc2a-492b-8e73-4e7b18ac113f' User entered 'None (1)'	System	08 Sep 2020 23:04:12
	System	08 Sep 2020 23:04:12

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:04:09', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '02f0ba23-dc2a-492b-8e73-4e7b18ac113f' User entered '08 Sep 2020 19:04'	System	08 Sep 2020 23:04:12
	System	08 Sep 2020 23:04:12

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 6'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:39:54', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'eea38284-6dc9-43da-9de1-b9f6aea6d7ee' User entered 'None (1)'	System	09 Sep 2020 23:40:09
	System	09 Sep 2020 23:40:09

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:39:57', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'eea38284-6dc9-43da-9de1-b9f6aea6d7ee' User entered 'No (N)'	System	09 Sep 2020 23:40:09
	System	09 Sep 2020 23:40:09

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:39:59', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'eea38284-6dc9-43da-9de1-b9f6aea6d7ee' User entered 'No (N)'	System	09 Sep 2020 23:40:09
	System	09 Sep 2020 23:40:09

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:40:02', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'eea38284-6dc9-43da-9de1-b9f6aea6d7ee' User entered 'None (1)'	System	09 Sep 2020 23:40:09
	System	09 Sep 2020 23:40:09

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:40:07', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'eea38284-6dc9-43da-9de1-b9f6aea6d7ee' User entered '09 Sep 2020 19:40'	System	09 Sep 2020 23:40:09
	System	09 Sep 2020 23:40:09

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 7'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:29', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e64b3a91-1d10-4579-ac3d-3046472c61dc' User entered 'None (1)'	System	10 Sep 2020 23:09:42
	System	10 Sep 2020 23:09:42

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:32', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e64b3a91-1d10-4579-ac3d-3046472c61dc' User entered 'No (N)'	System	10 Sep 2020 23:09:42
	System	10 Sep 2020 23:09:42

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:34', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e64b3a91-1d10-4579-ac3d-3046472c61dc' User entered 'No (N)'	System	10 Sep 2020 23:09:42
	System	10 Sep 2020 23:09:42

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:36', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e64b3a91-1d10-4579-ac3d-3046472c61dc' User entered 'None (1)'	System	10 Sep 2020 23:09:42
	System	10 Sep 2020 23:09:42

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:40', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e64b3a91-1d10-4579-ac3d-3046472c61dc' User entered '10 Sep 2020 19:09'	System	10 Sep 2020 23:09:42
	System	10 Sep 2020 23:09:42

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:53:31', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b7b94a3e-fcb2-4746-b2dd-825e58778318' User entered 'None (0)'	System	04 Sep 2020 15:53:58
	System	04 Sep 2020 15:53:58

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:53:34', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b7b94a3e-fcb2-4746-b2dd-825e58778318' User entered 'None (0)'	System	04 Sep 2020 15:53:58
	System	04 Sep 2020 15:53:58

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:53:36', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b7b94a3e-fcb2-4746-b2dd-825e58778318' User entered 'None (0)'	System	04 Sep 2020 15:53:58
	System	04 Sep 2020 15:53:58

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:53:40', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b7b94a3e-fcb2-4746-b2dd-825e58778318' User entered 'None (0)'	System	04 Sep 2020 15:53:58
	System	04 Sep 2020 15:53:58

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:53:43', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b7b94a3e-fcb2-4746-b2dd-825e58778318' User entered 'None (0)'	System	04 Sep 2020 15:53:58
	System	04 Sep 2020 15:53:58

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:53:45', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b7b94a3e-fcb2-4746-b2dd-825e58778318' User entered 'None (0)'	System	04 Sep 2020 15:53:58
	System	04 Sep 2020 15:53:58

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:53:52', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b7b94a3e-fcb2-4746-b2dd-825e58778318' User entered 'No (N)'	System	04 Sep 2020 15:53:58
	System	04 Sep 2020 15:53:58

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T11:53:56', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b7b94a3e-fcb2-4746-b2dd-825e58778318' User entered '04 Sep 2020 11:53'	System	04 Sep 2020 15:53:58
	System	04 Sep 2020 15:53:58

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '04 Sep 2020 11:13'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '04 Sep 2020 13:43'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:22', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '403702d1-a99e-4b6b-b5ce-c30b9b0cd5e0' User entered 'None (0)'	System	04 Sep 2020 18:41:49
	System	04 Sep 2020 18:41:49

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:24', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '403702d1-a99e-4b6b-b5ce-c30b9b0cd5e0' User entered 'None (0)'	System	04 Sep 2020 18:41:49
	System	04 Sep 2020 18:41:49

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:27', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '403702d1-a99e-4b6b-b5ce-c30b9b0cd5e0' User entered 'None (0)'	System	04 Sep 2020 18:41:49
	System	04 Sep 2020 18:41:49

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:29', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '403702d1-a99e-4b6b-b5ce-c30b9b0cd5e0' User entered 'None (0)'	System	04 Sep 2020 18:41:49
	System	04 Sep 2020 18:41:49

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:32', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '403702d1-a99e-4b6b-b5ce-c30b9b0cd5e0' User entered 'None (0)'	System	04 Sep 2020 18:41:49
	System	04 Sep 2020 18:41:49

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:34', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '403702d1-a99e-4b6b-b5ce-c30b9b0cd5e0' User entered 'None (0)'	System	04 Sep 2020 18:41:49
	System	04 Sep 2020 18:41:49

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:40', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '403702d1-a99e-4b6b-b5ce-c30b9b0cd5e0' User entered 'No (N)'	System	04 Sep 2020 18:41:49
	System	04 Sep 2020 18:41:49

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-04T14:41:46', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '403702d1-a99e-4b6b-b5ce-c30b9b0cd5e0' User entered '04 Sep 2020 14:41'	System	04 Sep 2020 18:41:49
	System	04 Sep 2020 18:41:49

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '04 Sep 2020 14:38'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 2'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T19:00:47', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '98ac9525-ffbf-431e-8dae-079f5516855e'	System	05 Sep 2020 23:01:29
User entered 'No interference with activity (1)'	System	05 Sep 2020 23:01:29

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T19:00:53', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '98ac9525-ffbf-431e-8dae-079f5516855e' User entered 'None (0)'	System	05 Sep 2020 23:01:29
	System	05 Sep 2020 23:01:29

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T19:01:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '98ac9525-ffbf-431e-8dae-079f5516855e'	System	05 Sep 2020 23:01:29
User entered 'No interference with activity (1)'	System	05 Sep 2020 23:01:29

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T19:01:05', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '98ac9525-ffbf-431e-8dae-079f5516855e' User entered 'None (0)'	System	05 Sep 2020 23:01:29
	System	05 Sep 2020 23:01:29

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T19:01:09', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '98ac9525-ffbf-431e-8dae-079f5516855e' User entered 'None (0)'	System	05 Sep 2020 23:01:29
	System	05 Sep 2020 23:01:29

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T19:01:11', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '98ac9525-ffbf-431e-8dae-079f5516855e' User entered 'None (0)'	System	05 Sep 2020 23:01:29
	System	05 Sep 2020 23:01:29

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T19:01:15', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '98ac9525-ffbf-431e-8dae-079f5516855e' User entered 'No (N)'	System	05 Sep 2020 23:01:29
	System	05 Sep 2020 23:01:29

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-05T19:01:26', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '98ac9525-ffbf-431e-8dae-079f5516855e' User entered '05 Sep 2020 19:01'	System	05 Sep 2020 23:01:29
	System	05 Sep 2020 23:01:29

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 3'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:27', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '8816d1ef-881e-4965-be81-13ec4739db4a' User entered 'None (0)'	System	06 Sep 2020 22:53:00
	System	06 Sep 2020 22:53:00

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:30', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '8816d1ef-881e-4965-be81-13ec4739db4a' User entered 'None (0)'	System	06 Sep 2020 22:53:00
	System	06 Sep 2020 22:53:00

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:33', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '8816d1ef-881e-4965-be81-13ec4739db4a' User entered 'None (0)'	System	06 Sep 2020 22:53:00
	System	06 Sep 2020 22:53:00

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:37', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '8816d1ef-881e-4965-be81-13ec4739db4a' User entered 'None (0)'	System	06 Sep 2020 22:53:00
	System	06 Sep 2020 22:53:00

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:39', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '8816d1ef-881e-4965-be81-13ec4739db4a' User entered 'None (0)'	System	06 Sep 2020 22:53:00
	System	06 Sep 2020 22:53:00

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:42', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '8816d1ef-881e-4965-be81-13ec4739db4a' User entered 'None (0)'	System	06 Sep 2020 22:53:00
	System	06 Sep 2020 22:53:00

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:47', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '8816d1ef-881e-4965-be81-13ec4739db4a' User entered 'No (N)'	System	06 Sep 2020 22:53:00
	System	06 Sep 2020 22:53:00

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-06T18:52:56', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '8816d1ef-881e-4965-be81-13ec4739db4a' User entered '06 Sep 2020 18:52'	System	06 Sep 2020 22:53:00
	System	06 Sep 2020 22:53:00

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 4'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T19:00:15', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9d0bc34d-bad6-43fb-94de-828fcf072094'	System	07 Sep 2020 23:00:38
User entered 'None (0)'	System	07 Sep 2020 23:00:38

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T19:00:20', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9d0bc34d-bad6-43fb-94de-828fcf072094' User entered 'None (0)'	System	07 Sep 2020 23:00:38
	System	07 Sep 2020 23:00:38

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T19:00:21', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9d0bc34d-bad6-43fb-94de-828fcf072094' User entered 'None (0)'	System	07 Sep 2020 23:00:38
	System	07 Sep 2020 23:00:38

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T19:00:24', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9d0bc34d-bad6-43fb-94de-828fcf072094' User entered 'None (0)'	System	07 Sep 2020 23:00:38
	System	07 Sep 2020 23:00:38

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T19:00:26', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9d0bc34d-bad6-43fb-94de-828fcf072094' User entered 'None (0)'	System	07 Sep 2020 23:00:38
	System	07 Sep 2020 23:00:38

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T19:00:28', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9d0bc34d-bad6-43fb-94de-828fcf072094' User entered 'None (0)'	System	07 Sep 2020 23:00:38
	System	07 Sep 2020 23:00:38

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T19:00:32', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9d0bc34d-bad6-43fb-94de-828fcf072094' User entered 'No (N)'	System	07 Sep 2020 23:00:38
	System	07 Sep 2020 23:00:38

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-07T19:00:36', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9d0bc34d-bad6-43fb-94de-828fcf072094' User entered '07 Sep 2020 19:00'	System	07 Sep 2020 23:00:38
	System	07 Sep 2020 23:00:38

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 5'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:04:14', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e847d90d-df1d-4cb2-b2a5-d5156916951a' User entered 'None (0)'	System	08 Sep 2020 23:04:39
	System	08 Sep 2020 23:04:39

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:04:16', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e847d90d-df1d-4cb2-b2a5-d5156916951a' User entered 'None (0)'	System	08 Sep 2020 23:04:39
	System	08 Sep 2020 23:04:39

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:04:19', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e847d90d-df1d-4cb2-b2a5-d5156916951a' User entered 'None (0)'	System	08 Sep 2020 23:04:39
	System	08 Sep 2020 23:04:39

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:04:22', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e847d90d-df1d-4cb2-b2a5-d5156916951a' User entered 'None (0)'	System	08 Sep 2020 23:04:39
	System	08 Sep 2020 23:04:39

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:04:24', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e847d90d-df1d-4cb2-b2a5-d5156916951a' User entered 'None (0)'	System	08 Sep 2020 23:04:39
	System	08 Sep 2020 23:04:39

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:04:26', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e847d90d-df1d-4cb2-b2a5-d5156916951a' User entered 'None (0)'	System	08 Sep 2020 23:04:39
	System	08 Sep 2020 23:04:39

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:04:29', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e847d90d-df1d-4cb2-b2a5-d5156916951a' User entered 'No (N)'	System	08 Sep 2020 23:04:39
	System	08 Sep 2020 23:04:39

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-08T19:04:37', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e847d90d-df1d-4cb2-b2a5-d5156916951a' User entered '08 Sep 2020 19:04'	System	08 Sep 2020 23:04:39
	System	08 Sep 2020 23:04:39

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 6'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:40:13', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f5c494e8-e048-4eab-9952-9eadec49f181' User entered 'None (0)'	System	09 Sep 2020 23:40:36
	System	09 Sep 2020 23:40:36

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:40:15', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f5c494e8-e048-4eab-9952-9eadec49f181' User entered 'None (0)'	System	09 Sep 2020 23:40:36
	System	09 Sep 2020 23:40:36

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:40:17', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f5c494e8-e048-4eab-9952-9eadec49f181' User entered 'None (0)'	System	09 Sep 2020 23:40:36
	System	09 Sep 2020 23:40:36

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:40:19', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f5c494e8-e048-4eab-9952-9eadec49f181' User entered 'None (0)'	System	09 Sep 2020 23:40:36
	System	09 Sep 2020 23:40:36

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:40:22', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f5c494e8-e048-4eab-9952-9eadec49f181' User entered 'None (0)'	System	09 Sep 2020 23:40:36
	System	09 Sep 2020 23:40:36

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:40:24', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f5c494e8-e048-4eab-9952-9eadec49f181' User entered 'None (0)'	System	09 Sep 2020 23:40:36
	System	09 Sep 2020 23:40:36

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:40:27', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f5c494e8-e048-4eab-9952-9eadec49f181' User entered 'No (N)'	System	09 Sep 2020 23:40:36
	System	09 Sep 2020 23:40:36

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-09T19:40:33', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f5c494e8-e048-4eab-9952-9eadec49f181' User entered '09 Sep 2020 19:40'	System	09 Sep 2020 23:40:36
	System	09 Sep 2020 23:40:36

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 7'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:45', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ba5ae7bb-99cc-49d2-9608-56c018298ba4' User entered 'None (0)'	System	10 Sep 2020 23:10:08
	System	10 Sep 2020 23:10:08

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:47', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ba5ae7bb-99cc-49d2-9608-56c018298ba4' User entered 'None (0)'	System	10 Sep 2020 23:10:08
	System	10 Sep 2020 23:10:08

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:48', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ba5ae7bb-99cc-49d2-9608-56c018298ba4' User entered 'None (0)'	System	10 Sep 2020 23:10:08
	System	10 Sep 2020 23:10:08

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:49', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ba5ae7bb-99cc-49d2-9608-56c018298ba4' User entered 'None (0)'	System	10 Sep 2020 23:10:08
	System	10 Sep 2020 23:10:08

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:51', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ba5ae7bb-99cc-49d2-9608-56c018298ba4' User entered 'None (0)'	System	10 Sep 2020 23:10:08
	System	10 Sep 2020 23:10:08

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:56', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ba5ae7bb-99cc-49d2-9608-56c018298ba4' User entered 'None (0)'	System	10 Sep 2020 23:10:08
	System	10 Sep 2020 23:10:08

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:09:59', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ba5ae7bb-99cc-49d2-9608-56c018298ba4' User entered 'No (N)'	System	10 Sep 2020 23:10:08
	System	10 Sep 2020 23:10:08

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-09-10T19:10:04', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ba5ae7bb-99cc-49d2-9608-56c018298ba4' User entered '10 Sep 2020 19:10'	System	10 Sep 2020 23:10:08
	System	10 Sep 2020 23:10:08

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:20:55

US3952004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:41:31
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	17 Sep 2020 15:26:58

US3952004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:41:31
User entered '11 Sep 2020'	Nick Bart (b) (4) (b) (4)	17 Sep 2020 15:26:58

US3952004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:41:31
User entered 'Contact Made (CONTACT MADE)'	Nick Bart (b) (4) (b) (4)	17 Sep 2020 15:26:58

US3952004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:41:31
User entered empty.	Nick Bart (b) (4) (b) (4)	17 Sep 2020 15:26:58

US3952004

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:58:46
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	17 Sep 2020 15:27:03

US3952004

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '1'	System	17 Sep 2020 15:27:03

US3952004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:13:43
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	25 Sep 2020 12:49:30

US3952004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
Protocol deviation 'Safety call visits not performed or out of window' inactivated.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:17:22
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 20:13:43
Protocol deviation created: Safety call visits not performed or out of window Class: Non-compliance with visit schedule Code: Deviation.	(b) (4), (b) (6)	08 Oct 2020 14:49:04
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 18:47:34
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Nick Bart (b) (4) (b) (4)	25 Sep 2020 12:49:43
answered with 'deviation filed' (Site from System). User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Sep 2020 12:49:30
User entered '22 Sep 2020'	Nick Bart (b) (4) (b) (4)	25 Sep 2020 12:49:30

US3952004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:13:43
User entered 'Contact Made (CONTACT MADE)'	Nick Bart (b) (4) (b) (4)	25 Sep 2020 12:49:30

US3952004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:13:43
User entered empty.	Nick Bart (b) (4) (b) (4)	25 Sep 2020 12:49:30

US3952004

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:13:36
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	25 Sep 2020 12:49:24

US3952004

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '1'	System	25 Sep 2020 12:49:24

US3952004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:13:25
User entered 'Yes (Y)'	Stephanie Melton (b) (4) (b) (4)	25 Sep 2020 19:57:11

US3952004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:13:25
User entered '25 Sep 2020'	Stephanie Melton (b) (4) (b) (4)	25 Sep 2020 19:57:11

US3952004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:13:25
User entered 'Contact Made (CONTACT MADE)'	Stephanie Melton (b) (4) (b) (4)	25 Sep 2020 19:57:11

US3952004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:13:25
User entered empty.	Stephanie Melton (b) (4) (b) (4)	25 Sep 2020 19:57:11

US3952004

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:12:06
User entered 'Yes (Y)'	Stephanie Melton (b) (4) (b) (4)	25 Sep 2020 19:57:16

US3952004

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:48:00
User entered '1'	System	25 Sep 2020 19:57:16

US3952004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:17:28
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:12:16

US3952004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:17:28
User entered '06 Oct 2020'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:12:16

US3952004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:17:28
User entered 'Clinic (Clinic)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:12:16

US3952004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'VISIT2'	System	07 Oct 2020 18:12:16

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '06 Oct 2020'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '08:31'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '06 Oct 2020 08:31'	System	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '37.0' C	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered 'Oral (Oral)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered empty.	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '70'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'bpm'	System	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '16'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'breaths/min'	System	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '113'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'mmHg'	System	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '66'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:32:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'mmHg'	System	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '06 Oct 2020'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '10:15'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '06 Oct 2020 10:15'	System	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '36.9' C	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered 'Oral (Oral)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered empty.	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '63'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'bpm'	System	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '14'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'breaths/min'	System	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '118'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'mmHg'	System	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:18:09
User entered '77'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:32:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'mmHg'	System	07 Oct 2020 18:13:44

US3952004

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:32:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:23:39
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:12:23

US3952004

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:32:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:23:39
User entered empty.	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:12:23

US3952004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:57
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	06 Oct 2020 14:07:58

US3952004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:57
User entered empty.	Brianne Okunji (b) (4) (b) (4)	06 Oct 2020 14:07:58

US3952004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:57
User entered empty.	Brianne Okunji (b) (4) (b) (4)	06 Oct 2020 14:07:58

US3952004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 14:07:58

US3952004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:57
User entered '06 Oct 2020'	Brianne Okunji (b) (4) (b) (4)	06 Oct 2020 14:07:58

US3952004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:57
User entered '09:35'	Brianne Okunji (b) (4) (b) (4)	06 Oct 2020 14:07:58

US3952004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '06 Oct 2020 09:35'	System	06 Oct 2020 14:07:58

US3952004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:27:57
User entered 'Left Arm (LEFT ARM)'	Brianne Okunji (b) (4) (b) (4)	06 Oct 2020 14:07:58

US3952004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 17:27:57
User entered 'ONCE'	System	06 Oct 2020 14:07:58

US3952004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:32:34

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 14:07:58

US3952004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:28:12
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:14:16

US3952004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:28:12
User entered '06 Oct 2020'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:14:16

US3952004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:28:12
User entered '09:07'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:14:16

US3952004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '06 Oct 2020 09:07'	System	07 Oct 2020 18:14:16

US3952004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:32:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:28:19
User entered '06 Oct 2020'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:14:29

US3952004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:32:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:14:29

US3952004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:32:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:28:19
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:14:29

US3952004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:32:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:28:19
User entered '09:09'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:14:29

US3952004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:32:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '06 Oct 2020 09:09'	System	07 Oct 2020 18:14:29

US3952004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:32:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:14:29

US3952004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:32:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:28:19
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:14:29

US3952004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:32:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:28:19
User entered empty.	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:14:29

US3952004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:32:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered empty.	System	07 Oct 2020 18:14:29

US3952004

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:28:57
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:12:28

US3952004

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '1'	System	07 Oct 2020 18:12:28

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:21:19', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '71edd33c-4b1c-4277-bb1c-633cf06f22ad' User entered 'Yes (Y)'	System	06 Oct 2020 14:21:40
	System	06 Oct 2020 14:21:40

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:21:28', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '71edd33c-4b1c-4277-bb1c-633cf06f22ad' User entered '98.3'	System	06 Oct 2020 14:21:40
	System	06 Oct 2020 14:21:40

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:21:32', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '71edd33c-4b1c-4277-bb1c-633cf06f22ad'	System	06 Oct 2020 14:21:40
User entered 'No (N)'	System	06 Oct 2020 14:21:40

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:21:38', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '71edd33c-4b1c-4277-bb1c-633cf06f22ad' User entered '06 Oct 2020 10:21'	System	06 Oct 2020 14:21:40
	System	06 Oct 2020 14:21:40

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Oct 2020 09:55'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Oct 2020 12:25'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:53:20', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e352e164-6ab6-4e34-b77d-65082c0c5af5' User entered 'Yes (Y)'	System	06 Oct 2020 19:53:38
	System	06 Oct 2020 19:53:38

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:53:27', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e352e164-6ab6-4e34-b77d-65082c0c5af5' User entered '97.9'	System	06 Oct 2020 19:53:38
	System	06 Oct 2020 19:53:38

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:53:31', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e352e164-6ab6-4e34-b77d-65082c0c5af5'	System	06 Oct 2020 19:53:38
User entered 'No (N)'	System	06 Oct 2020 19:53:38

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:53:35', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e352e164-6ab6-4e34-b77d-65082c0c5af5' User entered '06 Oct 2020 15:53'	System	06 Oct 2020 19:53:38
	System	06 Oct 2020 19:53:38

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Oct 2020 13:20'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 2'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:02:32', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ce9dbe57-fe74-442d-a6f4-d9e143b1ee56' User entered 'Yes (Y)'	System	07 Oct 2020 16:03:53
	System	07 Oct 2020 16:03:53

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:02:44', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ce9dbe57-fe74-442d-a6f4-d9e143b1ee56' User entered '100.7'	System	07 Oct 2020 16:03:53
	System	07 Oct 2020 16:03:53

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:02:48', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ce9dbe57-fe74-442d-a6f4-d9e143b1ee56'	System	07 Oct 2020 16:03:53
User entered 'No (N)'	System	07 Oct 2020 16:03:53

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:02:53', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ce9dbe57-fe74-442d-a6f4-d9e143b1ee56' User entered '07 Oct 2020 12:02'	System	07 Oct 2020 16:03:53
	System	07 Oct 2020 16:03:53

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 3'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:22:48', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '300047a0-3826-43d7-927f-1f2293edb59c' User entered 'Yes (Y)'	System	08 Oct 2020 21:23:06
	System	08 Oct 2020 21:23:06

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:22:54', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '300047a0-3826-43d7-927f-1f2293edb59c' User entered '98.2'	System	08 Oct 2020 21:23:06
	System	08 Oct 2020 21:23:06

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:22:57', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '300047a0-3826-43d7-927f-1f2293edb59c'	System	08 Oct 2020 21:23:06
User entered 'No (N)'	System	08 Oct 2020 21:23:06

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:04', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '300047a0-3826-43d7-927f-1f2293edb59c' User entered '08 Oct 2020 17:23'	System	08 Oct 2020 21:23:06
	System	08 Oct 2020 21:23:06

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 4'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:09:31', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9c05eb84-b63d-41e3-96f0-08edbc4d9a53' User entered 'Yes (Y)'	System	09 Oct 2020 17:09:47
	System	09 Oct 2020 17:09:47

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:09:36', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9c05eb84-b63d-41e3-96f0-08edbc4d9a53' User entered '97.5'	System	09 Oct 2020 17:09:47
	System	09 Oct 2020 17:09:47

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:09:40', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9c05eb84-b63d-41e3-96f0-08edbc4d9a53'	System	09 Oct 2020 17:09:47
User entered 'No (N)'	System	09 Oct 2020 17:09:47

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:09:44', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9c05eb84-b63d-41e3-96f0-08edbc4d9a53' User entered '09 Oct 2020 13:09'	System	09 Oct 2020 17:09:47
	System	09 Oct 2020 17:09:47

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 5'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:24:20', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ff049e89-d917-46b3-a4f5-18caa2a7231d' User entered 'Yes (Y)'	System	10 Oct 2020 23:24:38
	System	10 Oct 2020 23:24:38

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:24:30', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ff049e89-d917-46b3-a4f5-18caa2a7231d' User entered '97.9'	System	10 Oct 2020 23:24:38
	System	10 Oct 2020 23:24:38

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:24:34', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ff049e89-d917-46b3-a4f5-18caa2a7231d'	System	10 Oct 2020 23:24:38
User entered 'No (N)'	System	10 Oct 2020 23:24:38

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:24:37', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ff049e89-d917-46b3-a4f5-18caa2a7231d' User entered '10 Oct 2020 19:24'	System	10 Oct 2020 23:24:38
	System	10 Oct 2020 23:24:38

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 6'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd7ab12be-df89-491f-be7c-2cd45cf59c72' User entered 'Yes (Y)'	System	11 Oct 2020 16:02:52
	System	11 Oct 2020 16:02:52

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:09', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd7ab12be-df89-491f-be7c-2cd45cf59c72' User entered '97.1'	System	11 Oct 2020 16:02:52
	System	11 Oct 2020 16:02:52

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:12', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd7ab12be-df89-491f-be7c-2cd45cf59c72'	System	11 Oct 2020 16:02:52
User entered 'No (N)'	System	11 Oct 2020 16:02:52

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:16', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd7ab12be-df89-491f-be7c-2cd45cf59c72'	System	11 Oct 2020 16:02:52
User entered '11 Oct 2020 12:02'	System	11 Oct 2020 16:02:52

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 7'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:02:34', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e24ece68-1955-4826-b897-cb81a58e8de0' User entered 'Yes (Y)'	System	12 Oct 2020 16:02:49
	System	12 Oct 2020 16:02:49

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:02:40', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e24ece68-1955-4826-b897-cb81a58e8de0' User entered '98.3'	System	12 Oct 2020 16:02:49
	System	12 Oct 2020 16:02:49

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:02:43', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e24ece68-1955-4826-b897-cb81a58e8de0' User entered 'No (N)'	System	12 Oct 2020 16:02:49
	System	12 Oct 2020 16:02:49

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:02:47', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e24ece68-1955-4826-b897-cb81a58e8de0' User entered '12 Oct 2020 12:02'	System	12 Oct 2020 16:02:49
	System	12 Oct 2020 16:02:49

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:12:29', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7ed4b6b1-3dbf-49ee-9312-a5b81c446880' User entered 'None (1)'	System	06 Oct 2020 14:13:05
	System	06 Oct 2020 14:13:05

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:12:35', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7ed4b6b1-3dbf-49ee-9312-a5b81c446880' User entered 'No (N)'	System	06 Oct 2020 14:13:05
	System	06 Oct 2020 14:13:05

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:12:41', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7ed4b6b1-3dbf-49ee-9312-a5b81c446880' User entered 'No (N)'	System	06 Oct 2020 14:13:05
	System	06 Oct 2020 14:13:05

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:12:46', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7ed4b6b1-3dbf-49ee-9312-a5b81c446880' User entered 'None (1)'	System	06 Oct 2020 14:13:05
	System	06 Oct 2020 14:13:05

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:13:01', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7ed4b6b1-3dbf-49ee-9312-a5b81c446880' User entered '06 Oct 2020 10:13'	System	06 Oct 2020 14:13:05
	System	06 Oct 2020 14:13:05

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Oct 2020 09:55'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Oct 2020 12:25'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:53:42', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '04d55df4-f2fe-444b-bb96-29e331dbfb7a' User entered 'None (1)'	System	06 Oct 2020 19:53:57
	System	06 Oct 2020 19:53:57

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:53:46', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '04d55df4-f2fe-444b-bb96-29e331dbfb7a' User entered 'No (N)'	System	06 Oct 2020 19:53:57
	System	06 Oct 2020 19:53:57

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:53:48', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '04d55df4-f2fe-444b-bb96-29e331dbfb7a' User entered 'No (N)'	System	06 Oct 2020 19:53:57
	System	06 Oct 2020 19:53:57

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:53:52', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '04d55df4-f2fe-444b-bb96-29e331dbfb7a' User entered 'None (1)'	System	06 Oct 2020 19:53:57
	System	06 Oct 2020 19:53:57

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:53:55', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '04d55df4-f2fe-444b-bb96-29e331dbfb7a' User entered '06 Oct 2020 15:53'	System	06 Oct 2020 19:53:57
	System	06 Oct 2020 19:53:57

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Oct 2020 13:20'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 2'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:03:02', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ddd64acc-30f6-46d3-bcc4-28ab39ea072b' User entered 'None (1)'	System	07 Oct 2020 16:04:11
	System	07 Oct 2020 16:04:11

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:03:04', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ddd64acc-30f6-46d3-bcc4-28ab39ea072b' User entered 'No (N)'	System	07 Oct 2020 16:04:11
	System	07 Oct 2020 16:04:11

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:03:08', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ddd64acc-30f6-46d3-bcc4-28ab39ea072b' User entered 'No (N)'	System	07 Oct 2020 16:04:11
	System	07 Oct 2020 16:04:11

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:03:11', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ddd64acc-30f6-46d3-bcc4-28ab39ea072b' User entered 'None (1)'	System	07 Oct 2020 16:04:11
	System	07 Oct 2020 16:04:11

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:03:17', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'ddd64acc-30f6-46d3-bcc4-28ab39ea072b' User entered '07 Oct 2020 12:03'	System	07 Oct 2020 16:04:11
	System	07 Oct 2020 16:04:11

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 3'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:12', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e8b66d56-1eaa-4fa4-be7e-16506da5cd2a' User entered 'None (1)'	System	08 Oct 2020 21:23:27
	System	08 Oct 2020 21:23:27

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:16', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e8b66d56-1eaa-4fa4-be7e-16506da5cd2a' User entered 'No (N)'	System	08 Oct 2020 21:23:27
	System	08 Oct 2020 21:23:27

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:19', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e8b66d56-1eaa-4fa4-be7e-16506da5cd2a' User entered 'No (N)'	System	08 Oct 2020 21:23:27
	System	08 Oct 2020 21:23:27

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:21', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e8b66d56-1eaa-4fa4-be7e-16506da5cd2a' User entered 'None (1)'	System	08 Oct 2020 21:23:27
	System	08 Oct 2020 21:23:27

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:25', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e8b66d56-1eaa-4fa4-be7e-16506da5cd2a' User entered '08 Oct 2020 17:23'	System	08 Oct 2020 21:23:27
	System	08 Oct 2020 21:23:27

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 4'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:09:48', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f44da45d-a697-42e1-881e-afe2cc83fb9c' User entered 'None (1)'	System	09 Oct 2020 17:10:11
	System	09 Oct 2020 17:10:11

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:09:51', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f44da45d-a697-42e1-881e-afe2cc83fb9c' User entered 'No (N)'	System	09 Oct 2020 17:10:11
	System	09 Oct 2020 17:10:11

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:09:54', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f44da45d-a697-42e1-881e-afe2cc83fb9c' User entered 'No (N)'	System	09 Oct 2020 17:10:11
	System	09 Oct 2020 17:10:11

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:09:57', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f44da45d-a697-42e1-881e-afe2cc83fb9c' User entered 'None (1)'	System	09 Oct 2020 17:10:11
	System	09 Oct 2020 17:10:11

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:10:07', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f44da45d-a697-42e1-881e-afe2cc83fb9c' User entered '09 Oct 2020 13:10'	System	09 Oct 2020 17:10:11
	System	09 Oct 2020 17:10:11

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 5'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:24:41', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '63cfeb7d-d089-4e33-8ef6-8d3415f9657f' User entered 'None (1)'	System	10 Oct 2020 23:24:55
	System	10 Oct 2020 23:24:55

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:24:44', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '63cf7d-d089-4e33-8ef6-8d3415f9657f' User entered 'No (N)'	System	10 Oct 2020 23:24:55
	System	10 Oct 2020 23:24:55

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:24:46', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '63cf7d-d089-4e33-8ef6-8d3415f9657f' User entered 'No (N)'	System	10 Oct 2020 23:24:55
	System	10 Oct 2020 23:24:55

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:24:49', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '63cfeb7d-d089-4e33-8ef6-8d3415f9657f' User entered 'None (1)'	System	10 Oct 2020 23:24:55
	System	10 Oct 2020 23:24:55

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:24:51', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '63cf7d-d089-4e33-8ef6-8d3415f9657f' User entered '10 Oct 2020 19:24'	System	10 Oct 2020 23:24:55
	System	10 Oct 2020 23:24:55

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 6'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:22', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '226fa663-069a-49ba-861d-d07b53bdbc68'	System	11 Oct 2020 16:03:00
User entered 'None (1)'	System	11 Oct 2020 16:03:00

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:24', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '226fa663-069a-49ba-861d-d07b53bdbbc68' User entered 'No (N)'	System	11 Oct 2020 16:03:00
	System	11 Oct 2020 16:03:00

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:27', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '226fa663-069a-49ba-861d-d07b53bdbbc68' User entered 'No (N)'	System	11 Oct 2020 16:03:00
	System	11 Oct 2020 16:03:00

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:30', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '226fa663-069a-49ba-861d-d07b53bdbc68' User entered 'None (1)'	System	11 Oct 2020 16:03:00
	System	11 Oct 2020 16:03:00

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:32', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '226fa663-069a-49ba-861d-d07b53bdbc68' User entered '11 Oct 2020 12:02'	System	11 Oct 2020 16:03:00
	System	11 Oct 2020 16:03:00

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 7'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:02:51', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '05f1b6b8-98a9-4487-b18a-8a4bbe9cac73'	System	12 Oct 2020 16:03:09
User entered 'None (1)'	System	12 Oct 2020 16:03:09

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:02:53', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '05f1b6b8-98a9-4487-b18a-8a4bbe9cac73' User entered 'No (N)'	System	12 Oct 2020 16:03:09
	System	12 Oct 2020 16:03:09

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:02:56', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '05f1b6b8-98a9-4487-b18a-8a4bbe9cac73' User entered 'No (N)'	System	12 Oct 2020 16:03:09
	System	12 Oct 2020 16:03:09

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:02:58', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '05f1b6b8-98a9-4487-b18a-8a4bbe9cac73'	System	12 Oct 2020 16:03:09
User entered 'None (1)'	System	12 Oct 2020 16:03:09

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:03:04', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '05f1b6b8-98a9-4487-b18a-8a4bbe9cac73' User entered '12 Oct 2020 12:03'	System	12 Oct 2020 16:03:09
	System	12 Oct 2020 16:03:09

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:13:10', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0f254407-095c-412e-9179-7a14980230a7' User entered 'None (0)'	System	06 Oct 2020 14:13:37
	System	06 Oct 2020 14:13:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:13:14', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0f254407-095c-412e-9179-7a14980230a7' User entered 'None (0)'	System	06 Oct 2020 14:13:37
	System	06 Oct 2020 14:13:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:13:18', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0f254407-095c-412e-9179-7a14980230a7' User entered 'None (0)'	System	06 Oct 2020 14:13:37
	System	06 Oct 2020 14:13:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:13:20', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0f254407-095c-412e-9179-7a14980230a7' User entered 'None (0)'	System	06 Oct 2020 14:13:37
	System	06 Oct 2020 14:13:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:13:23', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0f254407-095c-412e-9179-7a14980230a7' User entered 'None (0)'	System	06 Oct 2020 14:13:37
	System	06 Oct 2020 14:13:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:13:26', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0f254407-095c-412e-9179-7a14980230a7' User entered 'None (0)'	System	06 Oct 2020 14:13:37
	System	06 Oct 2020 14:13:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:13:30', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0f254407-095c-412e-9179-7a14980230a7' User entered 'No (N)'	System	06 Oct 2020 14:13:37
	System	06 Oct 2020 14:13:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T10:13:34', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0f254407-095c-412e-9179-7a14980230a7' User entered '06 Oct 2020 10:13'	System	06 Oct 2020 14:13:37
	System	06 Oct 2020 14:13:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Oct 2020 09:55'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Oct 2020 12:25'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:54:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '172a61f7-c19d-4e95-94ab-e3d08d4874d5'	System	06 Oct 2020 19:54:18
User entered 'None (0)'	System	06 Oct 2020 19:54:18

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:54:02', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '172a61f7-c19d-4e95-94ab-e3d08d4874d5'	System	06 Oct 2020 19:54:18
User entered 'None (0)'	System	06 Oct 2020 19:54:18

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:54:04', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '172a61f7-c19d-4e95-94ab-e3d08d4874d5' User entered 'None (0)'	System	06 Oct 2020 19:54:18
	System	06 Oct 2020 19:54:18

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:54:07', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '172a61f7-c19d-4e95-94ab-e3d08d4874d5' User entered 'None (0)'	System	06 Oct 2020 19:54:18
	System	06 Oct 2020 19:54:18

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:54:09', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '172a61f7-c19d-4e95-94ab-e3d08d4874d5' User entered 'None (0)'	System	06 Oct 2020 19:54:18
	System	06 Oct 2020 19:54:18

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:54:11', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '172a61f7-c19d-4e95-94ab-e3d08d4874d5' User entered 'None (0)'	System	06 Oct 2020 19:54:18
	System	06 Oct 2020 19:54:18

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:54:14', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '172a61f7-c19d-4e95-94ab-e3d08d4874d5' User entered 'No (N)'	System	06 Oct 2020 19:54:18
	System	06 Oct 2020 19:54:18

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-06T15:54:16', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '172a61f7-c19d-4e95-94ab-e3d08d4874d5' User entered '06 Oct 2020 15:54'	System	06 Oct 2020 19:54:18
	System	06 Oct 2020 19:54:18

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '06 Oct 2020 13:20'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 2'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:03:26', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'da038fae-f13c-408b-8ecb-6554397d01dd' User entered 'None (0)'	System	07 Oct 2020 16:04:37
	System	07 Oct 2020 16:04:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:03:34', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'da038fae-f13c-408b-8ecb-6554397d01dd'	System	07 Oct 2020 16:04:37
User entered 'No interference with activity (1)'	System	07 Oct 2020 16:04:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:03:45', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'da038fae-f13c-408b-8ecb-6554397d01dd' User entered 'No interference with activity (1)'	System	07 Oct 2020 16:04:37
	System	07 Oct 2020 16:04:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:03:51', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'da038fae-f13c-408b-8ecb-6554397d01dd' User entered 'None (0)'	System	07 Oct 2020 16:04:37
	System	07 Oct 2020 16:04:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:03:59', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'da038fae-f13c-408b-8ecb-6554397d01dd'	System	07 Oct 2020 16:04:37
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	07 Oct 2020 16:04:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:04:03', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'da038fae-f13c-408b-8ecb-6554397d01dd' User entered 'None (0)'	System	07 Oct 2020 16:04:37
	System	07 Oct 2020 16:04:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:04:07', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'da038fae-f13c-408b-8ecb-6554397d01dd' User entered 'No (N)'	System	07 Oct 2020 16:04:37
	System	07 Oct 2020 16:04:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-07T12:04:13', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'da038fae-f13c-408b-8ecb-6554397d01dd' User entered '07 Oct 2020 12:04'	System	07 Oct 2020 16:04:37
	System	07 Oct 2020 16:04:37

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 3'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:30', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '20f7f631-92a4-400f-b3d7-b2cdf53e79ff'	System	08 Oct 2020 21:23:52
User entered 'None (0)'	System	08 Oct 2020 21:23:52

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:33', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '20f7f631-92a4-400f-b3d7-b2cdf53e79ff'	System	08 Oct 2020 21:23:52
User entered 'None (0)'	System	08 Oct 2020 21:23:52

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:35', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '20f7f631-92a4-400f-b3d7-b2cdf53e79ff' User entered 'None (0)'	System	08 Oct 2020 21:23:52
	System	08 Oct 2020 21:23:52

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:37', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '20f7f631-92a4-400f-b3d7-b2cdf53e79ff' User entered 'None (0)'	System	08 Oct 2020 21:23:52
	System	08 Oct 2020 21:23:52

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:40', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '20f7f631-92a4-400f-b3d7-b2cdf53e79ff' User entered 'None (0)'	System	08 Oct 2020 21:23:52
	System	08 Oct 2020 21:23:52

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:43', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '20f7f631-92a4-400f-b3d7-b2cdf53e79ff'	System	08 Oct 2020 21:23:52
User entered 'None (0)'	System	08 Oct 2020 21:23:52

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:45', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '20f7f631-92a4-400f-b3d7-b2cdf53e79ff' User entered 'No (N)'	System	08 Oct 2020 21:23:52
	System	08 Oct 2020 21:23:52

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-08T17:23:49', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '20f7f631-92a4-400f-b3d7-b2cdf53e79ff' User entered '08 Oct 2020 17:23'	System	08 Oct 2020 21:23:52
	System	08 Oct 2020 21:23:52

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 4'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:10:12', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '83de20a2-d3ee-4dc8-bcda-2dc6a21eda61' User entered 'None (0)'	System	09 Oct 2020 17:10:33
	System	09 Oct 2020 17:10:33

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:10:14', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '83de20a2-d3ee-4dc8-bcda-2dc6a21eda61' User entered 'None (0)'	System	09 Oct 2020 17:10:33
	System	09 Oct 2020 17:10:33

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:10:15', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '83de20a2-d3ee-4dc8-bcda-2dc6a21eda61' User entered 'None (0)'	System	09 Oct 2020 17:10:33
	System	09 Oct 2020 17:10:33

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:10:18', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '83de20a2-d3ee-4dc8-bcda-2dc6a21eda61' User entered 'None (0)'	System	09 Oct 2020 17:10:33
	System	09 Oct 2020 17:10:33

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:10:20', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '83de20a2-d3ee-4dc8-bcda-2dc6a21eda61' User entered 'None (0)'	System	09 Oct 2020 17:10:33
	System	09 Oct 2020 17:10:33

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:10:24', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '83de20a2-d3ee-4dc8-bcda-2dc6a21eda61' User entered 'None (0)'	System	09 Oct 2020 17:10:33
	System	09 Oct 2020 17:10:33

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:10:28', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '83de20a2-d3ee-4dc8-bcda-2dc6a21eda61' User entered 'No (N)'	System	09 Oct 2020 17:10:33
	System	09 Oct 2020 17:10:33

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-09T13:10:31', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '83de20a2-d3ee-4dc8-bcda-2dc6a21eda61' User entered '09 Oct 2020 13:10'	System	09 Oct 2020 17:10:33
	System	09 Oct 2020 17:10:33

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 5'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:24:56', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e013f0b3-5345-4809-83fc-57102a0f7315' User entered 'None (0)'	System	10 Oct 2020 23:25:14
	System	10 Oct 2020 23:25:14

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:24:58', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e013f0b3-5345-4809-83fc-57102a0f7315' User entered 'None (0)'	System	10 Oct 2020 23:25:14
	System	10 Oct 2020 23:25:14

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:25:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e013f0b3-5345-4809-83fc-57102a0f7315' User entered 'None (0)'	System	10 Oct 2020 23:25:14
	System	10 Oct 2020 23:25:14

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:25:02', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e013f0b3-5345-4809-83fc-57102a0f7315' User entered 'None (0)'	System	10 Oct 2020 23:25:14
	System	10 Oct 2020 23:25:14

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:25:03', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e013f0b3-5345-4809-83fc-57102a0f7315' User entered 'None (0)'	System	10 Oct 2020 23:25:14
	System	10 Oct 2020 23:25:14

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:25:05', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e013f0b3-5345-4809-83fc-57102a0f7315' User entered 'None (0)'	System	10 Oct 2020 23:25:14
	System	10 Oct 2020 23:25:14

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:25:08', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e013f0b3-5345-4809-83fc-57102a0f7315' User entered 'No (N)'	System	10 Oct 2020 23:25:14
	System	10 Oct 2020 23:25:14

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-10T19:25:11', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e013f0b3-5345-4809-83fc-57102a0f7315' User entered '10 Oct 2020 19:25'	System	10 Oct 2020 23:25:14
	System	10 Oct 2020 23:25:14

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 6'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:36', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5f32160b-786c-4f8d-976c-128c078f6797' User entered 'None (0)'	System	11 Oct 2020 16:03:12
	System	11 Oct 2020 16:03:12

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:38', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5f32160b-786c-4f8d-976c-128c078f6797' User entered 'None (0)'	System	11 Oct 2020 16:03:12
	System	11 Oct 2020 16:03:12

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:39', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5f32160b-786c-4f8d-976c-128c078f6797' User entered 'None (0)'	System	11 Oct 2020 16:03:12
	System	11 Oct 2020 16:03:12

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:41', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5f32160b-786c-4f8d-976c-128c078f6797' User entered 'None (0)'	System	11 Oct 2020 16:03:12
	System	11 Oct 2020 16:03:12

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:43', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5f32160b-786c-4f8d-976c-128c078f6797' User entered 'None (0)'	System	11 Oct 2020 16:03:12
	System	11 Oct 2020 16:03:12

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:44', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5f32160b-786c-4f8d-976c-128c078f6797' User entered 'None (0)'	System	11 Oct 2020 16:03:12
	System	11 Oct 2020 16:03:12

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:47', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5f32160b-786c-4f8d-976c-128c078f6797' User entered 'No (N)'	System	11 Oct 2020 16:03:12
	System	11 Oct 2020 16:03:12

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-11T12:02:49', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5f32160b-786c-4f8d-976c-128c078f6797' User entered '11 Oct 2020 12:02'	System	11 Oct 2020 16:03:12
	System	11 Oct 2020 16:03:12

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
Data entry locked.	System	06 Oct 2020 14:07:58
User entered 'Day 7'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:03:09', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5eee959a-8942-4065-b685-de7a2635013f' User entered 'None (0)'	System	12 Oct 2020 16:03:29
	System	12 Oct 2020 16:03:29

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:03:12', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5eee959a-8942-4065-b685-de7a2635013f' User entered 'None (0)'	System	12 Oct 2020 16:03:29
	System	12 Oct 2020 16:03:29

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:03:15', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5eee959a-8942-4065-b685-de7a2635013f' User entered 'None (0)'	System	12 Oct 2020 16:03:29
	System	12 Oct 2020 16:03:29

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:03:17', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5eee959a-8942-4065-b685-de7a2635013f' User entered 'None (0)'	System	12 Oct 2020 16:03:29
	System	12 Oct 2020 16:03:29

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:03:19', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5eee959a-8942-4065-b685-de7a2635013f' User entered 'None (0)'	System	12 Oct 2020 16:03:29
	System	12 Oct 2020 16:03:29

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:03:21', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5eee959a-8942-4065-b685-de7a2635013f' User entered 'None (0)'	System	12 Oct 2020 16:03:29
	System	12 Oct 2020 16:03:29

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

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 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:03:24', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5eee959a-8942-4065-b685-de7a2635013f' User entered 'No (N)'	System	12 Oct 2020 16:03:29
	System	12 Oct 2020 16:03:29

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-10-12T12:03:27', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5eee959a-8942-4065-b685-de7a2635013f' User entered '12 Oct 2020 12:03'	System	12 Oct 2020 16:03:29
	System	12 Oct 2020 16:03:29

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 14:07:58

US3952004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:32:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:14
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 14:07:58

US3952004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:20:31
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	15 Oct 2020 17:40:07

US3952004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:20:31
User entered '13 Oct 2020'	Nick Bart (b) (4) (b) (4)	15 Oct 2020 17:40:07

US3952004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:20:31
User entered 'Contact Made (CONTACT MADE)'	Nick Bart (b) (4) (b) (4)	15 Oct 2020 17:40:07

US3952004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:20:31
User entered empty.	Nick Bart (b) (4) (b) (4)	15 Oct 2020 17:40:07

US3952004

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:20:34
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	15 Oct 2020 17:39:51

US3952004

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '1'	System	15 Oct 2020 17:39:51

US3952004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:20:59
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 03NOV2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 10:46:24
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 03NOV2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' answered with 'Unscheduled Kit used to collect samples, only scheduled Visit 3 specimens collected' (Site from DM).	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:40:29
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 03NOV2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 01:07:26
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	22 Oct 2020 16:22:04

US3952004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:20:59
User entered '20 Oct 2020'	Nick Bart (b) (4) (b) (4)	22 Oct 2020 16:22:04

US3952004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:20:59
User entered 'Contact Made (CONTACT MADE)'	Nick Bart (b) (4) (b) (4)	22 Oct 2020 16:22:04

US3952004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:20:59
User entered empty.	Nick Bart (b) (4) (b) (4)	22 Oct 2020 16:22:04

US3952004

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:21:11
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	22 Oct 2020 16:22:11

US3952004

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '1'	System	22 Oct 2020 16:22:11

US3952004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:21:18
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	12 Nov 2020 23:10:50

US3952004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:21:18
User entered '27 Oct 2020'	Brianne Okunji (b) (4) (b) (4)	12 Nov 2020 23:10:50

US3952004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:21:18
User entered 'Contact Made (CONTACT MADE)'	Brianne Okunji (b) (4) (b) (4)	12 Nov 2020 23:10:50

US3952004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:21:18
User entered empty.	Brianne Okunji (b) (4) (b) (4)	12 Nov 2020 23:10:50

US3952004

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:24:31
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	12 Nov 2020 23:10:01

US3952004

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '1'	System	12 Nov 2020 23:10:01

US3952004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:25:18
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:44:52

US3952004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:25:18
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Nov 2020 21:44:58
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	16 Nov 2020 21:44:58
User entered '03 Nov 2020' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:44:58
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Nov 2020 21:44:52
User entered '16 Nov 2020'	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:44:52

US3952004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:25:18
User entered 'Clinic (Clinic)'	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:44:52

US3952004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'VISIT3'	System	16 Nov 2020 21:44:52

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User closed query 'Per page 3 of Visit 3 source, subject did have vital signs. Please enter.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:38:30
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 21:38:14
Query 'Per page 3 of Visit 3 source, subject did have vital signs. Please enter.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:17
User opened query 'Per page 3 of Visit 3 source, subject did have vital signs. Please enter.' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 20:31:31
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:38:14
User entered '03 Nov 2020' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:17
User entered empty.	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:38:14
User entered '08:14' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:17
User entered empty.	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '03 Nov 2020 08:14'	System	08 Feb 2021 15:04:17
User entered empty.	System	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:38:14
User entered '36.8' C reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:17
User entered empty.	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:38:14
User entered 'Oral (Oral)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:17
User entered empty.	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:38:14
User entered empty.	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:38:14
User entered '68' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:17
User entered empty.	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'bpm'	System	08 Feb 2021 15:04:17
User entered empty.	System	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:38:14
User entered '14' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:17
User entered empty.	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'breaths/min'	System	08 Feb 2021 15:04:17
User entered empty.	System	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:38:14
User entered '133' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:17
User entered empty.	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'mmHg'	System	08 Feb 2021 15:04:17
User entered empty.	System	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:38:14
User entered '72' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:17
User entered empty.	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered 'mmHg'	System	08 Feb 2021 15:04:17
User entered empty.	System	16 Nov 2020 21:45:15

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52

US3952004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52

US3952004

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:32:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:31:35
User entered 'No (N)'	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:23

US3952004

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:32:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:31:35
User entered empty.	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:23

US3952004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:32:33
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:48

US3952004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:32:33
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03-Nov-2020 is recorded under Visit 3 Day 57 in EDC; however, immuno sample is reported under "Unscheduled" visit in PPD portal. Please reconcile the correct Visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 09:46:33
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03-Nov-2020 is recorded under Visit 3 Day 57 in EDC; however, immuno sample is reported under "Unscheduled" visit in PPD portal. Please reconcile the correct Visit and update if applicable, else clarify.' answered with 'Unscheduled Kit used to collect samples. Only scheduled assessments performed' (Site from DM).	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:43:26
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03-Nov-2020 is recorded under Visit 3 Day 57 in EDC; however, immuno sample is reported under "Unscheduled" visit in PPD portal. Please reconcile the correct Visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 07:12:20
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 21:45:58
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		16 Nov 2020 21:45:58
User entered '03 Nov 2020' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:58
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 21:45:48

US3952004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:48

US3952004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:32:33
User entered '08:17'	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:45:48

US3952004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '03 Nov 2020 08:17'	System	16 Nov 2020 21:45:58
User entered '16 Nov 2020 08:17'	System	16 Nov 2020 21:45:48

US3952004

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:32:56
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	16 Nov 2020 21:46:03

US3952004

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '1'	System	16 Nov 2020 21:46:03

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:26
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 64'	System	04 Sep 2020 15:20:55

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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)	26 Feb 2021 02:05:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-07T18:29:07', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '33aced3b-ce1e-4edd-9e05-3706faa093c4' User entered 'No (N)'	System	07 Nov 2020 23:29:40
	System	07 Nov 2020 23:29:40

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with 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)	26 Feb 2021 02:05:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-07T18:29:16', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '33aced3b-ce1e-4edd-9e05-3706faa093c4'	System	07 Nov 2020 23:29:40
User entered 'No (N)'	System	07 Nov 2020 23:29:40

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-07T18:29:37', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '33aced3b-ce1e-4edd-9e05-3706faa093c4' User entered '07 Nov 2020 18:29:37'	System	07 Nov 2020 23:29:40
	System	07 Nov 2020 23:29:40

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:26
Data entry locked.	System	04 Sep 2020 15:20:55
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 15:20:55

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:26
Data entry locked.	System	04 Sep 2020 15:20:55
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:26
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 71'	System	04 Sep 2020 15:20:55

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

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)	26 Feb 2021 02:05:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-13T12:00:13', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e930b40a-2547-4377-9a18-f88117cbdca6' User entered 'No (N)'	System	13 Nov 2020 17:00:47
	System	13 Nov 2020 17:00:47

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with 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)	26 Feb 2021 02:05:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-13T12:00:16', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e930b40a-2547-4377-9a18-f88117cbdca6'	System	13 Nov 2020 17:00:47
User entered 'No (N)'	System	13 Nov 2020 17:00:47

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-13T12:00:22', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'e930b40a-2547-4377-9a18-f88117cbdca6' User entered '13 Nov 2020 12:00:22'	System	13 Nov 2020 17:00:47
	System	13 Nov 2020 17:00:47

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:26
Data entry locked.	System	04 Sep 2020 15:20:55
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 15:20:55

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:26
Data entry locked.	System	04 Sep 2020 15:20:55
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:26
Data entry locked.	System	04 Sep 2020 15:20:55
User entered 'Day 78'	System	04 Sep 2020 15:20:55

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[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)	26 Feb 2021 02:05:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-18T07:34:24', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'c8b24ea9-ceaa-479a-956d-fc6dd5f60671' User entered 'No (N)'	System	18 Nov 2020 12:34:38
	System	18 Nov 2020 12:34:38

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with 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)	26 Feb 2021 02:05:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-18T07:34:30', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'c8b24ea9-ceaa-479a-956d-fc6dd5f60671' User entered 'No (N)'	System	18 Nov 2020 12:34:38
	System	18 Nov 2020 12:34:38

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-18T07:34:36', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'c8b24ea9-ceaa-479a-956d-fc6dd5f60671' User entered '18 Nov 2020 07:34:36'	System	18 Nov 2020 12:34:38
	System	18 Nov 2020 12:34:38

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:26
Data entry locked.	System	04 Sep 2020 15:20:55
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 15:20:55

US3952004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:05:26
Data entry locked.	System	04 Sep 2020 15:20:55
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 15:20:55

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-19T18:39:21', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '4b6d460d-4740-4a72-b526-55b355d7f829'	System	19 Nov 2020 23:39:41
User entered 'No (N)'	System	19 Nov 2020 23:39:41

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-19T18:39:25', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '4b6d460d-4740-4a72-b526-55b355d7f829'	System	19 Nov 2020 23:39:41
User entered 'No (N)'	System	19 Nov 2020 23:39:41

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-19T18:39:38', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '4b6d460d-4740-4a72-b526-55b355d7f829'	System	19 Nov 2020 23:39:41
User entered '19 Nov 2020 18:39:38'	System	19 Nov 2020 23:39:41

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-22T14:30:52', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '592a9f0b-5a18-4be1-8a65-e6a6ecc2d194'	System	22 Nov 2020 19:31:05
User entered 'No (N)'	System	22 Nov 2020 19:31:05

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-22T14:30:57', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '592a9f0b-5a18-4be1-8a65-e6a6ecc2d194'	System	22 Nov 2020 19:31:05
User entered 'No (N)'	System	22 Nov 2020 19:31:05

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-22T14:31:02', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '592a9f0b-5a18-4be1-8a65-e6a6ecc2d194' User entered '22 Nov 2020 14:31:02'	System	22 Nov 2020 19:31:05
	System	22 Nov 2020 19:31:05

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-29T19:37:01', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd5ddf51d-4337-4d94-8cf4-f081a7616ebf' User entered 'No (N)'	System	30 Nov 2020 00:37:12

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-29T19:37:06', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd5ddf51d-4337-4d94-8cf4-f081a7616ebf'	System	30 Nov 2020 00:37:12
User entered 'No (N)'	System	30 Nov 2020 00:37:12

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-11-29T19:37:10', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd5ddf51d-4337-4d94-8cf4-f081a7616ebf' User entered '29 Nov 2020 19:37:10'	System	30 Nov 2020 00:37:12
	System	30 Nov 2020 00:37:12

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-12-07T18:37:37', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'da4b6f72-a636-4660-be58-bdc893827337'	System	07 Dec 2020 23:37:49
User entered 'No (N)'	System	07 Dec 2020 23:37:49

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-12-07T18:37:40', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'da4b6f72-a636-4660-be58-bdc893827337'	System	07 Dec 2020 23:37:49
User entered 'No (N)'	System	07 Dec 2020 23:37:49

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-12-07T18:37:44', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'da4b6f72-a636-4660-be58-bdc893827337' User entered '07 Dec 2020 18:37:44'	System	07 Dec 2020 23:37:49
	System	07 Dec 2020 23:37:49

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-12-13T20:27:24', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'dbecb1cc-6125-45a1-88a6-bcd7f9dcca75'	System	14 Dec 2020 01:27:33
User entered 'No (N)'	System	14 Dec 2020 01:27:33

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-12-13T20:27:27', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'dbecb1cc-6125-45a1-88a6-bcd7f9dcca75'	System	14 Dec 2020 01:27:33
User entered 'No (N)'	System	14 Dec 2020 01:27:33

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-12-13T20:27:30', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'dbecb1cc-6125-45a1-88a6-bcd7f9dcca75' User entered '13 Dec 2020 20:27:30'	System	14 Dec 2020 01:27:33
	System	14 Dec 2020 01:27:33

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-12-20T00:02:02', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '11712394-88fd-4d0b-bda0-399629fb6426' User entered 'No (N)'	System	20 Dec 2020 05:02:33
	System	20 Dec 2020 05:02:33

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-12-20T00:02:07', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '11712394-88fd-4d0b-bda0-399629fb6426'	System	20 Dec 2020 05:02:33
User entered 'No (N)'	System	20 Dec 2020 05:02:33

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-12-20T00:02:13', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '11712394-88fd-4d0b-bda0-399629fb6426' User entered '20 Dec 2020 00:02:13'	System	20 Dec 2020 05:02:33
	System	20 Dec 2020 05:02:33

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-12-27T01:43:54', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0dbaaf47-793c-4899-873d-3c97e3312e94'	System	27 Dec 2020 06:44:09
User entered 'No (N)'	System	27 Dec 2020 06:44:09

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-12-27T01:42:27', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0dbaaf47-793c-4899-873d-3c97e3312e94'	System	27 Dec 2020 06:44:09
User entered 'No (N)'	System	27 Dec 2020 06:44:09

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2020-12-27T01:44:08', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0dbaaf47-793c-4899-873d-3c97e3312e94' User entered '27 Dec 2020 01:44:08'	System	27 Dec 2020 06:44:09
	System	27 Dec 2020 06:44:09

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-01-03T00:02:37', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'c772cd03-f7f9-4c87-819e-b5daf097b7f9'	System	03 Jan 2021 05:03:13
User entered 'No (N)'	System	03 Jan 2021 05:03:13

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-01-03T00:02:41', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'c772cd03-f7f9-4c87-819e-b5daf097b7f9'	System	03 Jan 2021 05:03:13
User entered 'No (N)'	System	03 Jan 2021 05:03:13

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-01-03T00:02:50', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'c772cd03-f7f9-4c87-819e-b5daf097b7f9' User entered '03 Jan 2021 00:02:50'	System	03 Jan 2021 05:03:13
	System	03 Jan 2021 05:03:13

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-01-10T00:01:48', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f0929cdd-26bb-46c6-b42a-b11db915ecc7'	System	10 Jan 2021 05:02:40
User entered 'No (N)'	System	10 Jan 2021 05:02:40

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-01-10T00:01:51', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f0929cdd-26bb-46c6-b42a-b11db915ecc7'	System	10 Jan 2021 05:02:40
User entered 'No (N)'	System	10 Jan 2021 05:02:40

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-01-10T00:02:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f0929cdd-26bb-46c6-b42a-b11db915ecc7' User entered '10 Jan 2021 00:02:00'	System	10 Jan 2021 05:02:40
	System	10 Jan 2021 05:02:40

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-01-19T12:17:13', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '8569e6f6-07db-4f01-be86-457f8b26314e' User entered 'No (N)'	System	19 Jan 2021 17:17:25
	System	19 Jan 2021 17:17:25

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-01-19T12:17:16', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '8569e6f6-07db-4f01-be86-457f8b26314e'	System	19 Jan 2021 17:17:25
User entered 'No (N)'	System	19 Jan 2021 17:17:25

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-01-19T12:17:21', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '8569e6f6-07db-4f01-be86-457f8b26314e' User entered '19 Jan 2021 12:17:21'	System	19 Jan 2021 17:17:25
	System	19 Jan 2021 17:17:25

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-01-24T08:25:17', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9b790901-bfd9-401a-812c-8fef8cb2a266'	System	24 Jan 2021 13:25:28
User entered 'No (N)'	System	24 Jan 2021 13:25:28

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-01-24T08:25:21', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9b790901-bfd9-401a-812c-8fef8cb2a266'	System	24 Jan 2021 13:25:28
User entered 'No (N)'	System	24 Jan 2021 13:25:28

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-01-24T08:25:25', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '9b790901-bfd9-401a-812c-8fef8cb2a266'	System	24 Jan 2021 13:25:28
User entered '24 Jan 2021 08:25:25'	System	24 Jan 2021 13:25:28

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-02T12:08:55', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'bf439c45-8a12-4f3a-acd9-0f305d36117a' User entered 'No (N)'	System	02 Feb 2021 17:13:08

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-02T12:09:06', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'bf439c45-8a12-4f3a-acd9-0f305d36117a'	System	02 Feb 2021 17:13:08
User entered 'No (N)'	System	02 Feb 2021 17:13:08

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-02T12:09:11', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'bf439c45-8a12-4f3a-acd9-0f305d36117a' User entered '02 Feb 2021 12:09:11'	System	02 Feb 2021 17:13:08
	System	02 Feb 2021 17:13:08

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-09T12:03:17', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7f059661-9b27-42e9-91c4-460d66b7f01e'	System	09 Feb 2021 17:09:26
User entered 'No (N)'	System	09 Feb 2021 17:09:26

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-09T12:03:19', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7f059661-9b27-42e9-91c4-460d66b7f01e'	System	09 Feb 2021 17:09:26
User entered 'No (N)'	System	09 Feb 2021 17:09:26

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-09T12:03:27', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7f059661-9b27-42e9-91c4-460d66b7f01e' User entered '09 Feb 2021 12:03:27'	System	09 Feb 2021 17:09:26
	System	09 Feb 2021 17:09:26

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-14T18:50:26', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '961f1539-8cb8-4a15-8200-a236cc90a5e3' User entered 'No (N)'	System	14 Feb 2021 23:50:38

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-14T18:50:29', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '961f1539-8cb8-4a15-8200-a236cc90a5e3' User entered 'No (N)'	System	14 Feb 2021 23:50:38

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-14T18:50:35', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '961f1539-8cb8-4a15-8200-a236cc90a5e3' User entered '14 Feb 2021 18:50:35'	System	14 Feb 2021 23:50:38
	System	14 Feb 2021 23:50:38

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-21T00:07:23', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5afa59f6-7abc-42ea-b450-4a4bc46fa05b'	System	21 Feb 2021 05:07:38
User entered 'No (N)'	System	21 Feb 2021 05:07:38

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-21T00:07:28', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5afa59f6-7abc-42ea-b450-4a4bc46fa05b'	System	21 Feb 2021 05:07:38
User entered 'No (N)'	System	21 Feb 2021 05:07:38

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-21T00:07:33', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '5afa59f6-7abc-42ea-b450-4a4bc46fa05b' User entered '21 Feb 2021 00:07:33'	System	21 Feb 2021 05:07:38
	System	21 Feb 2021 05:07:38

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-28T00:12:00-05:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '87d06a05-c104-4ce2-ae02-84068dd8cb3d' User entered 'No (N)'	System	28 Feb 2021 05:12:15
	System	28 Feb 2021 05:12:15

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-28T00:12:04-05:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '87d06a05-c104-4ce2-ae02-84068dd8cb3d'	System	28 Feb 2021 05:12:15
User entered 'No (N)'	System	28 Feb 2021 05:12:15

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-28T00:12:09-05:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '87d06a05-c104-4ce2-ae02-84068dd8cb3d'	System	28 Feb 2021 05:12:15
User entered '28 Feb 2021 05:12:09'	System	28 Feb 2021 05:12:15

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-03-07T00:02:40-05:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'eb91cf30-2668-4db1-b38b-a74bf5c7550c'	System	07 Mar 2021 05:04:54
User entered 'No (N)'	System	07 Mar 2021 05:04:54

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-03-07T00:02:45-05:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'eb91cf30-2668-4db1-b38b-a74bf5c7550c'	System	07 Mar 2021 05:04:54
User entered 'No (N)'	System	07 Mar 2021 05:04:54

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-03-07T00:03:02-05:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'eb91cf30-2668-4db1-b38b-a74bf5c7550c' User entered '07 Mar 2021 00:03:02'	System	07 Mar 2021 05:04:54
	System	07 Mar 2021 05:04:54

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-03-14T00:02:35-05:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '667493b5-5811-4956-ba97-6def38c0ea31'	System	14 Mar 2021 05:06:56
User entered 'No (N)'	System	14 Mar 2021 05:06:56

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-03-14T00:02:39-05:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '667493b5-5811-4956-ba97-6def38c0ea31'	System	14 Mar 2021 05:06:56
User entered 'No (N)'	System	14 Mar 2021 05:06:56

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-03-14T00:02:50-05:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '667493b5-5811-4956-ba97-6def38c0ea31'	System	14 Mar 2021 05:06:56
User entered '14 Mar 2021 00:02:50'	System	14 Mar 2021 05:06:56

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-03-21T18:39:41-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'eac787df-ca5c-40dc-a05d-cce6ff0c8c36'	System	21 Mar 2021 22:39:52
User entered 'No (N)'	System	21 Mar 2021 22:39:52

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-03-21T18:39:44-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'eac787df-ca5c-40dc-a05d-cce6ff0c8c36'	System	21 Mar 2021 22:39:52
User entered 'No (N)'	System	21 Mar 2021 22:39:52

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-03-21T18:39:50-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'eac787df-ca5c-40dc-a05d-cce6ff0c8c36'	System	21 Mar 2021 22:39:52
User entered '21 Mar 2021 18:39:50'	System	21 Mar 2021 22:39:52

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-03-28T13:42:42-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7e3b41b3-a9e9-4d06-8b53-adc3af40c0ce' User entered 'No (N)'	System	28 Mar 2021 17:42:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-03-28T13:42:45-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7e3b41b3-a9e9-4d06-8b53-adc3af40c0ce'	System	28 Mar 2021 17:42:59
User entered 'No (N)'	System	28 Mar 2021 17:42:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-03-28T13:42:52-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '7e3b41b3-a9e9-4d06-8b53-adc3af40c0ce' User entered '28 Mar 2021 13:42:52'	System	28 Mar 2021 17:42:59
	System	28 Mar 2021 17:42:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-04-04T13:47:03-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd52c8b91-16a4-40ad-949e-83669e78c564'	System	07 Apr 2021 13:45:16
User entered 'No (N)'	System	07 Apr 2021 13:45:16

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-04-04T13:47:07-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd52c8b91-16a4-40ad-949e-83669e78c564'	System	07 Apr 2021 13:45:16
User entered 'No (N)'	System	07 Apr 2021 13:45:16

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-04-04T13:47:12-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'd52c8b91-16a4-40ad-949e-83669e78c564'	System	07 Apr 2021 13:45:16
User entered '04 Apr 2021 13:47:12'	System	07 Apr 2021 13:45:16

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-04-11T10:34:12-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b5c3d7b3-8f22-486d-abee-dad46fae29f2'	System	11 Apr 2021 14:34:25
User entered 'No (N)'	System	11 Apr 2021 14:34:25

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-04-11T10:34:15-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b5c3d7b3-8f22-486d-abee-dad46fae29f2'	System	11 Apr 2021 14:34:25
User entered 'No (N)'	System	11 Apr 2021 14:34:25

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-04-11T10:34:20-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b5c3d7b3-8f22-486d-abee-dad46fae29f2'	System	11 Apr 2021 14:34:25
User entered '11 Apr 2021 10:34:20'	System	11 Apr 2021 14:34:25

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-04-18T08:00:16-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f8cd9275-f164-405d-a16c-7dc6f1185b30'	System	18 Apr 2021 12:00:30
User entered 'No (N)'	System	18 Apr 2021 12:00:30

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-04-18T08:00:20-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f8cd9275-f164-405d-a16c-7dc6f1185b30'	System	18 Apr 2021 12:00:30
User entered 'No (N)'	System	18 Apr 2021 12:00:30

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-04-18T08:00:25-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'f8cd9275-f164-405d-a16c-7dc6f1185b30'	System	18 Apr 2021 12:00:30
User entered '18 Apr 2021 08:00:25'	System	18 Apr 2021 12:00:30

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-04-25T00:02:47-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0907aa09-a73b-4166-9f67-57550e26f993'	System	25 Apr 2021 04:03:59
User entered 'No (N)'	System	25 Apr 2021 04:03:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-04-25T00:02:53-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0907aa09-a73b-4166-9f67-57550e26f993'	System	25 Apr 2021 04:03:59
User entered 'No (N)'	System	25 Apr 2021 04:03:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-04-25T00:03:03-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: '0907aa09-a73b-4166-9f67-57550e26f993'	System	25 Apr 2021 04:03:59
User entered '25 Apr 2021 00:03:03'	System	25 Apr 2021 04:03:59

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-05-02T08:22:17-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'c2d6ebe2-db21-4429-bfeb-707a07718a06'	System	02 May 2021 12:22:26
User entered 'No (N)'	System	02 May 2021 12:22:26

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-05-02T08:22:12-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'c2d6ebe2-db21-4429-bfeb-707a07718a06'	System	02 May 2021 12:22:26
User entered 'No (N)'	System	02 May 2021 12:22:26

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-05-02T08:22:20-04:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'c2d6ebe2-db21-4429-bfeb-707a07718a06'	System	02 May 2021 12:22:26
User entered '02 May 2021 08:22:20'	System	02 May 2021 12:22:26

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '06 Nov 2022 00:01'	System	19 Nov 2020 19:46:22

US3952004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:32:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:46:22
Amendment Manager: User entered '10 Nov 2022 23:59'	System	19 Nov 2020 19:46:22

US3952004

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:32:34

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:34:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-28T00:12:23-05:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b4d1e666-5133-437c-b772-95ef425f5d29'	System	28 Feb 2021 05:12:35
User entered 'No (N)'	System	28 Feb 2021 05:12:35

US3952004

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:32:34

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:34:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3F1645D-A021-4413-8C28-359FD70039E0)', Time: '2021-02-28T00:12:31-05:00', User OID: 'PatientReportedOutcome (US3952004)', ODM File OID: 'b4d1e666-5133-437c-b772-95ef425f5d29' User entered '28 Feb 2021 05:12:31'	System	28 Feb 2021 05:12:35
	System	28 Feb 2021 05:12:35

US3952004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:47:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 23:36:22

US3952004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:47:33
User entered '02 Dec 2020'	(b) (4), (b) (6)	02 Dec 2020 23:36:22

US3952004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:47:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Dec 2020 23:36:22

US3952004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:47:33
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 23:36:22

US3952004

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:47:46
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 17:47:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:47:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 23:36:31

US3952004

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:52
User entered '1'	System	02 Dec 2020 23:36:31

US3952004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:49:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 14:57:55

US3952004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:49:41
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	05 Jan 2021 14:58:10
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	05 Jan 2021 14:58:10
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	05 Jan 2021 14:58:10
User entered '05 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 14:58:10
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	05 Jan 2021 14:57:55
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	05 Jan 2021 14:57:55
User entered '05 Jan 2020'	(b) (4), (b) (6)	05 Jan 2021 14:57:55

US3952004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:49:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Jan 2021 14:57:55

US3952004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:49:41
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 14:57:55

US3952004

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:49:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 14:58:17

US3952004

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User entered '1'	System	05 Jan 2021 14:58:17

US3952004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:59:21
User entered 'Yes (Y)'	chrishea Harvey (b) (4)	03 Feb 2021 15:17:54

US3952004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:59:21
User entered '03 Feb 2021'	chrishea Harvey (b) (4)	03 Feb 2021 15:17:54

US3952004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:59:21
User entered 'Contact Made (CONTACT MADE)'	chrishea Harvey (b) (4)	03 Feb 2021 15:17:54

US3952004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:59:21
User entered empty.	chrishea Harvey (b) (4)	03 Feb 2021 15:17:54

US3952004

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:59:24
User entered 'Yes (Y)'	chrishea Harvey (b) (4)	03 Feb 2021 15:18:00

US3952004

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User entered '1'	System	03 Feb 2021 15:18:00

US3952004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:00:39
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:47:38

US3952004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:00:39
User entered empty.	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:47:38

US3952004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:00:39
User entered empty.	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:47:38

US3952004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:32:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:00:39
User entered empty.	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:47:38

US3952004

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:00:43
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:48:29

US3952004

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:36:26
User entered '1'	System	12 Mar 2021 20:48:29

US3952004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:59:51
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:28:29

US3952004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:59:51
User entered '23 Mar 2021'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:28:29

US3952004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:59:51
User entered 'Clinic (Clinic)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:28:29

US3952004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User entered 'VISIT4'	System	29 Mar 2021 16:28:29

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:09
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:09
User entered '23 Mar 2021'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:09
User entered '08:48'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User entered '23 Mar 2021 08:48'	System	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:09
User entered '37.2' C	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:09
User entered 'Oral (Oral)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:09
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:09
User entered '74'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User entered 'bpm'	System	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:09
User entered '16'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User entered 'breaths/min'	System	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:09
User entered '119'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User entered 'mmHg'	System	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:09
User entered '63'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User entered 'mmHg'	System	29 Mar 2021 16:29:07

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59

US3952004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:32:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59

US3952004

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:32:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:20
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:28:45

US3952004

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:32:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:20
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:28:45

US3952004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:31
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:28:40

US3952004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:31
User entered '23 Mar 2021'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:28:40

US3952004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:31
User entered '09:06'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:28:40

US3952004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User entered '23 Mar 2021 09:06'	System	29 Mar 2021 16:28:40

US3952004

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:01:19
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:28:32

US3952004

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:32:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:59
User entered '1'	System	29 Mar 2021 16:28:32

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:53:07
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:45

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:53:07
User entered '04 Feb 2021'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:45

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:53:07
User entered 'Clinic (Clinic)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:04:45

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:32:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User entered 'UNBLND_DECIDE'	System	08 Feb 2021 15:04:45

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:32:34

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:55:35
User entered '04 Feb 2021'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:02

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:32:34

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:52:08

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:32:34

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:55:35
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:02

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:32:34

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
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 17:52:08

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:32:34

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:55:35
User entered '04 Feb 2021'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:02

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:32:34

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:55:35
User entered 'mRNA-1273 (mRNA-1273)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:02

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:32:34

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:55:35
User entered 'mRNA-1273 (mRNA-1273)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:02

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:32:34

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:55:35
User entered 'mRNA-1273 (mRNA-1273)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:02

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:32:34

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:55:35
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:02

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:32:34

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User entered empty.	System	08 Feb 2021 15:05:02

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:32:34

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User entered empty.	System	08 Feb 2021 15:05:02

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:41
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:11

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:41
User entered '04 Feb 2021'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:11

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:41
User entered '14:45'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:11

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:32:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User entered '04 Feb 2021 14:45'	System	08 Feb 2021 15:05:11

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:32:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:49
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:20

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:32:34

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:49
User entered '04 Feb 2021'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:20

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:32:34

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:58:49
User entered '14:48'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:05:20

US3952004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:32:34

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:26:52
User entered '04 Feb 2021 14:48'	System	08 Feb 2021 15:05:20

US3952004

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:32:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:52
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:02:59
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:06:21
User entered 'Yes (Y)'	(b) (4)	08 Feb 2021 18:06:01
	Mimi Van Der Leden	
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:20:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:54
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:37
User entered	System	09 Feb 2021 13:13:30
'USA-US215-2021-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	09 Feb 2021 13:13:30

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spondylolisthesis, LLT: Spondylolisthesis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 12:45:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 12:45:03
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden (b) (4)	08 Feb 2021 18:14:26
Data point term sent to Coder	System	08 Feb 2021 18:13:59
User entered 'Worsening of degenerative spondylolithesis'	Mimi Van Der Leden (b) (4)	08 Feb 2021 18:13:14

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered 'Yes (Y)'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered 'No (N)'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered 'No (N)'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered '22 Nov 2020'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered empty.	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 18:13:14

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered 'No (N)'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:20:18
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User closed query 'PV query: Please consider updating the end date for the event considering that the subject remained hospitalized until 24 Dec 2020 and received treatment including pain medication after 22 Dec 2020. ' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 14:48:47
Query 'PV query: Please consider updating the end date for the event considering that the subject remained hospitalized until 24 Dec 2020 and received treatment including pain medication after 22 Dec 2020. ' answered with 'end date updated' (Site from Safety).	Mimi Van Der Leden	25 Mar 2021 12:57:25
	(b) (4)	
Signature has been broken.	Mimi Van Der Leden	25 Mar 2021 12:57:10
	(b) (4)	
User entered '24 Dec 2020' reason for change: Data Entry Error	Mimi Van Der Leden	25 Mar 2021 12:57:10
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 17:35:09
User opened query 'PV query: Please consider updating the end date for the event considering that the subject remained hospitalized until 24 Dec 2020 and received treatment including pain medication after 22 Dec 2020. ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 11:25:49
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered '22 Dec 2020'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered empty.	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 18:13:14

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered 'Yes (Y)'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered '0'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered '0'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered '1'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered '22 Dec 2020'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered '24 Dec 2020'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered 'No (N)'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered empty.	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered '0'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered '0'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered '0'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

US3952004

Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:20:18
User closed query 'Per DM CLR: Re query: Response noted however no corresponding medication is updated. Kindly update the CM page as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 12:09:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:42:31
Query 'Per DM CLR: Re query: Response noted however no corresponding medication is updated. Kindly update the CM page as appropriate. Thank you.' answered with 'updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:06:20
User opened query 'Per DM CLR: Re query: Response noted however no corresponding medication is updated. Kindly update the CM page as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 10:24:48
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 10:24:48
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'CM list to be updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:46:38
DataPoint Un-verified.	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:45:04
Signature has been broken.	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:45:04
User entered '0' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:45:04
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 08:18:30
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Feb 2021 18:14:07
User entered '1' reason for change: Data Entry Error	Mimi Van Der Leden	08 Feb 2021 18:14:07
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Feb 2021 18:13:14
User entered '0'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:20:18
User closed query 'Per CDM: Concomitant Medication is recorded "Yes". However there is no corresponding CM Medication record in Prior / concomitant Medication and Vaccination with same start date and end date. Please review and update accordingly or else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 12:10:16
Query 'Per CDM: Concomitant Medication is recorded "Yes". However there is no corresponding CM Medication record in Prior / concomitant Medication and Vaccination with same start date and end date. Please review and update accordingly or else clarify. ' answered with 'CM updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:06:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:22:23
User opened query 'Per CDM: Concomitant Medication is recorded "Yes". However there is no corresponding CM Medication record in Prior / concomitant Medication and Vaccination with same start date and end date. Please review and update accordingly or else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:11:58
DataPoint Un-verified.	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:45:04
Signature has been broken.	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:45:04
User entered '1' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:45:04
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden (b) (4)	08 Feb 2021 18:14:26
User entered '0'	Mimi Van Der Leden (b) (4)	08 Feb 2021 18:13:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:20:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 19:42:39
User closed query 'Please select concomitant procedure as subject had surgery.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:42:34
Query 'Please select concomitant procedure as subject had surgery.' answered with 'updated' (Site from CRA).	Mimi Van Der Leden	25 Mar 2021 12:58:42
	(b) (4)	
Signature has been broken.	Mimi Van Der Leden	25 Mar 2021 12:58:12
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Mimi Van Der Leden	25 Mar 2021 12:58:12
	(b) (4)	
User opened query 'Please select concomitant procedure as subject had surgery.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 17:27:05
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 17:26:51
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered '0'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:49
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 18:14:26
	(b) (4)	
User entered empty.	Mimi Van Der Leden	08 Feb 2021 18:13:14
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:20:18
DataPoint Verified.	(b) (4)	07 Apr 2021 18:19:40
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Narrative = MECHANICAL DVT PROPHYLAXIS WITH TED STOCKS AND SCDS WERE USED. However, this 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)	30 Mar 2021 13:09:03
User closed query 'Per DM CLR: Narrative = SUBJECT RECEIVED PERI-OPERATIVE ANCEF. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:08:59
User closed query 'Per DM CLR: Narrative = SHE UNDERWENT GENERAL ANESTHESIA. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:08:57
Query 'Per DM CLR: Narrative = MECHANICAL DVT PROPHYLAXIS WITH TED STOCKS AND SCDS WERE USED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'All procedures added to eCRF per records' (Site from DM).	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:28:03
Query 'Per DM CLR: Narrative = SUBJECT RECEIVED PERI-OPERATIVE ANCEF. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'CM updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:04:39
Query 'Per DM CLR: Narrative = SHE UNDERWENT GENERAL ANESTHESIA. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'CM updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:04:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = MECHANICAL DVT PROPHYLAXIS WITH TED STOCKS AND SCDS WERE USED. However, this 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)	29 Mar 2021 00:20:25
User opened query 'Per DM CLR: Narrative = SUBJECT RECEIVED PERI-OPERATIVE ANCEP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 00:20:19
User opened query 'Per DM CLR: Narrative = SHE UNDERWENT GENERAL ANESTHESIA. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 00:20:14
User closed query 'Per DM CLR: SAE Narrative = FURTHER DETAILS WILL BE PROVIDED UPON RECEIPT OF MEDICAL RECORDS. HOSPITAL RECORDS RECEIVED AND COURSE OF HOSPITALIZATION IS OUTLINED. SUBJECT WAS ADMITTED FOR ELECTIVE L4-L5 LAMINECTOMY AND FUSION. SHE UNDERWENT GENERAL ANESTHESIA AND SURGERY WAS PERFORMED WITHOUT COMPLICATION. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 09:39:53
User closed query 'Please add XR L-Spine 1 performed on 22Dec20 pre and post-op in narrative and in concomitant procedures.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 17:22:31
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)	15 Mar 2021 13:20:15

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 13:20:12
User closed query 'PV Query: Please confirm treatment dates (27 Dec 2020) for hydrocodone and Tylenol which began after event resolution. ' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 13:19:59
Query 'Per DM CLR: SAE Narrative = FURTHER DETAILS WILL BE PROVIDED UPON RECEIPT OF MEDICAL RECORDS. HOSPITAL RECORDS RECEIVED AND COURSE OF HOSPITALIZATION IS OUTLINED. SUBJECT WAS ADMITTED FOR ELECTIVE L4-L5 LAMINECTOMY AND FUSION. SHE UNDERWENT GENERAL ANESTHESIA AND SURGERY WAS PERFORMED WITHOUT COMPLICATION. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'Please clarify what eCRF this data should be entered under' (Site from DM).	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:46:10
Query 'Please add XR L-Spine 1 performed on 22Dec20 pre and post-op in narrative and in concomitant procedures.' answered with 'added' (Site from CRA).	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:44:49
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 'Covid-19 negative as of 19Dec2020' (Site from Safety).	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:42:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'faxed and emailed 12Mar2021' (Site from Safety).	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:41:53
Query 'PV Query: Please confirm treatment dates (27 Dec 2020) for hydrocodone and Tylenol which began after event resolution. ' answered with 'This was treatment post-op pain for the dates specified' (Site from Safety).	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:41:38
User opened query 'Per DM CLR: SAE Narrative = FURTHER DETAILS WILL BE PROVIDED UPON RECEIPT OF MEDICAL RECORDS. HOSPITAL RECORDS RECEIVED AND COURSE OF HOSPITALIZATION IS OUTLINED. SUBJECT WAS ADMITTED FOR ELECTIVE L4-L5 LAMINECTOMY AND FUSION. SHE UNDERWENT GENERAL ANESTHESIA AND SURGERY WAS PERFORMED WITHOUT COMPLICATION. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	12 Mar 2021 08:19:00
User opened query 'Please add XR L-Spine 1 performed on 22Dec20 pre and post-op in narrative and in concomitant procedures.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	08 Mar 2021 17:46:46
User closed query 'Consider spelling of last (spelled las) in the final sentence of the narrative.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	08 Mar 2021 16:16:37
Query 'Consider spelling of last (spelled las) in the final sentence of the narrative.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4) (b) (4)	04 Mar 2021 15:08:32
Signature has been broken.	Nick Bart (b) (4) (b) (4)	04 Mar 2021 15:08:27

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS HX OF WORSENING DEGENERATIVE SPONDYLOLISTHESIS, INITIALLY DIAGNOSED IN 2010. SHE WAS ADMITTED TO HOSPITAL ON 22DEC2020 FOR A LUMBAR SPINAL FUSION. HAD AN UNEVENTFUL COURSE AND WAS DISCHARGED ON 24DEC2020. FURTHER DETAILS WILL BE PROVIDED UPON RECEIPT OF MEDICAL RECORDS. HOSPITAL RECORDS RECEIVED AND COURSE OF HOSPITALIZATION IS OUTLINED. SUBJECT WAS ADMITTED FOR ELECTIVE L4-L5 LAMINECTOMY AND FUSION. SHE UNDERWENT GENERAL ANESTHESIA AND SURGERY WAS PERFORMED WITHOUT COMPLICATION. SUBJECT RECEIVED PERI-OPERATIVE ANCEF UNTIL POST OP DAY 2 WHEN SURGICAL DRAIN WAS REMOVED. MECHANICAL DVT PROPHYLAXIS WITH TED STOCKS AND SCDS WERE USED. ON DAY OF DISCHARGE SUBJECT WAS DOING WELL WITH PAIN CONTROLLED ON AN ORAL REGIMEN. SHE WAS EVALUATED BY PT AND CLEARED FOR DISCHARGE TO HOME ON 24DEC2020. SUBJECT WAS SEEN IN RESEARCH SITE FOR VISIT LAST WEEK AND NOTED TO BE DOING VERY WELL.' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	04 Mar 2021 15:08:27
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)	16 Feb 2021 17:43:16
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:43:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm treatment dates (27 Dec 2020) for hydrocodone and Tylenol which began after event resolution. ' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:42:50
User opened query 'Consider spelling of last (spelled las) in the final sentence of the narrative.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 15:02:55
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 15:02:03
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:01:58
User signature succeeded.	Mimi Van Der Leden	08 Feb 2021 20:49:51
Signature has been broken.	(b) (4)	
	Mimi Van Der Leden	08 Feb 2021 20:48:21
	(b) (4)	
User entered 'SUBJECT HAS HX OF WORSENING DEGENERATIVE SPONDYLOLISTHESIS, INITIALLY DIAGNOSED IN 2010. SHE WAS ADMITTED TO HOPSPITAL ON 22DEC2020 FOR A LUMBAR SPINAL FUSION. HAD AN UNEVENTFUL COURSE AND WAS DISCHARGED ON 24DEC2020. FURTHER DETAILS WILL BE PROVIDED UPON RECEIPT OF MEDICAL RECORDS. Hospital Records received and course of hospitalization is outlined. Subject was admitted for elective L4-L5 laminectomy and fusion. She underwent general anesthesia and surgery was performed without complication. Subject received peri-operative ancef until post op day 2 when surgical drain was removed. Mechanical DVT prophylaxis with TED stocks and SCDS were used. On day of discharge subject was doing well with pain controlled on an oral regimen. She was evaluated by PT and cleared for discharge to home on 24Dec2020. Subject was seen in research site for visit las week and noted to be doing very well.' reason for change: Data Entry Error	Mimi Van Der Leden	08 Feb 2021 20:48:21
User signature succeeded.	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject has hx of worsening degenerative spondylolisthesis, initially diagnosed in 2010. She was admitted to hospital on 22Dec2020 for a lumbar spinal fusion. Had an uneventful course and was discharged on 24Dec2020. Further details will be provided upon receipt of medical records.'	Mimi Van Der Leden (b) (4)	08 Feb 2021 18:13:14

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Folder: Adverse Events

Form: Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 18:13:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 18:13:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:32:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Feb 2021 18:13:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:32:34

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:25:14
User closed query 'Please add percocet and valium from SAE listed in the medical records.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:25:13
Query 'Please add percocet and valium from SAE listed in the medical records.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:09:13
User opened query 'Please add percocet and valium from SAE listed in the medical records.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 17:34:40
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 17:34:08
User closed query 'Please add new medications to EDC.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:41:30
Query 'Please add new medications to EDC.' answered with 'CM updated' (Site from CRA).	Nick Bart (b) (4) (b) (4)	27 Jan 2021 20:39:55
User opened query 'Please add new medications to EDC.' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 20:42:23
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:30:40
User closed query 'Please add Amlopidine and Influenza vaccine.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:30:36
Query 'Please add Amlopidine and Influenza vaccine.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:30:54
User opened query 'Please add Amlopidine and Influenza vaccine.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 20:08:30
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 20:07:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:32:34

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:14:44
User entered 'Yes (Y)'	Nick Bart (b) (4)	09 Sep 2020 20:54:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 20:56:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 20:56:43
	(b) (4)	
Data point term sent to Coder	System	09 Sep 2020 20:55:48
User entered 'famotidine'	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'gerd'	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '40'	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:55:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'once daily (QD)'	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'un UNK 2015'	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 20:55:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:55:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:55:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 20:55:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 20:56:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 20:56:44
	(b) (4)	
Data point term sent to Coder	System	09 Sep 2020 20:55:47
User entered 'montelukast'	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'seasonal allergies'	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '10'	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'mg (mg)'	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'once daily (QD)'	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'un UNK 2010'	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 20:55:28
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:55:28

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:55:28

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 20:55:28

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 20:57:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 20:57:42
	(b) (4)	
Data point term sent to Coder User entered 'rosuvastatin'	System	09 Sep 2020 20:56:49
	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'hyperlipidemia'	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '10'	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'mg (mg)'	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'once daily (QD)'	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'un UNK 2015'	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 20:56:04
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:56:04

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:56:04

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 20:56:04

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 07:14:39
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 Sep 2020 07:14:39
Data point term sent to Coder	System	09 Sep 2020 20:57:54
User entered 'diclofenac'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'herniated lumbar disks'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '75'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'once daily (QD)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Oral (ORAL)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'un May 2020'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)' reason for change: New Information	Nick Bart (b) (4) (b) (4)	22 Oct 2020 16:23:49
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '16 Oct 2020' reason for change: New Information	Nick Bart (b) (4) (b) (4)	22 Oct 2020 16:23:49
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User entered '1'	System	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User entered '1'	System	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:14
User entered '804 (804)'	System	09 Sep 2020 20:57:37

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: STEROIDS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 07:33:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 07:33:31
	(b) (4)	
Data point term sent to Coder	System	09 Sep 2020 20:58:56
User entered 'steroid injection'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'herniated lumbar disks'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '1'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Other (OTHER)'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'dose'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'other (OTHER)'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'every two months'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Other (OTHER)'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'spinal'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '12 Jun 2020'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 20:58:45
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:58:45

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:58:45

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:58:45

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 15:01:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 15:01:32
	(b) (4)	
Data point term sent to Coder	System	08 Feb 2021 15:01:16
Coding entries removed.	Nick Bart (b) (4)	08 Feb 2021 15:00:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 16:30:17
User closed query 'Please write out to ASA.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 16:30:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:23
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:23
	(b) (4)	
Data point term sent to Coder	System	21 Dec 2020 14:27:15
Query 'Please write out to ASA.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	21 Dec 2020 14:26:23
	(b) (4)	
Coding entries removed.	Nick Bart (b) (4)	21 Dec 2020 14:26:19
	(b) (4)	
User entered 'Acetylsalicylic Acid' reason for change: Per Query Resolution	Nick Bart (b) (4)	21 Dec 2020 14:26:19
	(b) (4)	
User opened query 'Please write out to ASA.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 19:50:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 19:49:32
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:00:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:00:47
Data point term sent to Coder User entered 'asa'	System Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:00:01 09 Sep 2020 20:59:22

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	10 Feb 2021 19:03:18
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	09 Feb 2021 08:44:30
' (Site from DM).		
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	Nick Bart (b) (4)	08 Feb 2021 15:00:54
' answered with 'updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Nick Bart (b) (4)	08 Feb 2021 15:00:49
	(b) (4)	
User entered 'cardiac PROPHYLAXIS' reason for change: Data Entry Error	Nick Bart (b) (4)	08 Feb 2021 15:00:49
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	02 Feb 2021 03:27:03
' (Site from DM).		
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	20 Nov 2020 08:36:19
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	18 Nov 2020 07:12:20
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'prophylaxis'	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '81'	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'mg (mg)'	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'once daily (QD)'	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'un UNK 2015'	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:22

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 20:59:22
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:59:22

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:59:22

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 20:59:22

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:00:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:00:47
Data point term sent to Coder	System	09 Sep 2020 21:00:03
User entered 'amlodipine'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'hypertension'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User closed query 'Per ConMed log, this is discrepant. Please confirm and update if necessary.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:30:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:34:42
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg, 2.5mg, 5 mg) or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 08:48:46
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg, 2.5mg, 5 mg) or provide explanation for alternate dosage.' answered with 'updated. 1.5 tablets at 5mg per tablet' (Site from DM).	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:28:10
Query 'Per ConMed log, this is discrepant. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:27:59
User entered '7.5' reason for change: Per Query Resolution	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:27:55
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg, 2.5mg, 5 mg) or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:13:39
User opened query 'Per ConMed log, this is discrepant. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 19:52:03
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '75'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'once daily (QD)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Oral (ORAL)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'un Sep 2019'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User closed query 'Per ConMed list, does not match source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:36:14
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:36:11
Query 'Per ConMed list, does not match source.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:28:39
User entered 'No (N)' reason for change: New Information	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:28:34
User opened query 'Per ConMed list, does not match source.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 19:52:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User closed query 'Per ConMed list, does not match source. Please confirm and update if needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:36:16
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:36:13
Query 'Per ConMed list, does not match source. Please confirm and update if needed.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:28:42
User entered '19 Oct 2020' reason for change: New Information	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:28:34
User opened query 'Per ConMed list, does not match source. Please confirm and update if needed.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 19:53:57
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 19:52:46
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User entered '1'	System	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User entered '1'	System	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:07
User entered '804 (804)'	System	09 Sep 2020 20:59:57

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: BETAXOLOL HYDROCHLORIDE, PRODUCTSYNONYM: BETOPTIC - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 05:36:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 05:36:49
Data point term sent to Coder	System	09 Sep 2020 21:02:06
User entered 'Betoptic 0.25%'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:01:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'glaucoma'	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '1'	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Other (OTHER)'	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'drop per eye'	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'twice daily (BID)'	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Intraocular (INTRAOCULAR)'	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'un UNK 2000'	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 21:01:06
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Sep 2020 21:01:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 21:01:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 21:01:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE, PRODUCTSYNONYM: DYMISTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 21:02:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 21:02:44
	(b) (4)	
Data point term sent to Coder	System	09 Sep 2020 21:02:10
User entered 'dymista'	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'seasonal allergies'	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '137-50'	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'ug (ug)'	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'once daily (QD)'	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Nasal (NASAL)'	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'un UNK 2015'	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 21:02:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 21:02:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 21:02:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 21:02:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 21:04:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 21:04:43
	(b) (4)	
Data point term sent to Coder	System	09 Sep 2020 21:03:13
User entered 'escitalopram oxalate'	Nick Bart (b) (4)	09 Sep 2020 21:02:42
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 21:02:42
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'depression'	Nick Bart (b) (4)	09 Sep 2020 21:02:42
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '10'	Nick Bart (b) (4)	09 Sep 2020 21:02:42
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:02:42

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:02:42
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'once daily (QD)'	Nick Bart (b) (4)	09 Sep 2020 21:02:42
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:02:42

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	09 Sep 2020 21:02:42
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:02:42
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'un UNK 2017'	Nick Bart (b) (4)	09 Sep 2020 21:02:42
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4)	09 Sep 2020 21:02:42
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:02:42

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:02:42
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 21:02:42
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 21:02:42

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 21:02:42

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 21:02:42

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
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)	09 Sep 2020 21:06:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:06:00
Data point term sent to Coder	System	09 Sep 2020 21:04:18
User entered 'doxycycline'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 08:49:03
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'MH listing present for Rosacea' (Site from DM).	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:30:24
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:15:36
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'rosacea'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '40'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'once daily (QD)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Oral (ORAL)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '04 Sep 2020'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)' reason for change: New Information	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:16:15
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '22 Sep 2020' reason for change: New Information	Nick Bart (b) (4) (b) (4)	07 Oct 2020 18:16:15
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User entered '1'	System	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User entered '1'	System	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User entered '804 (804)'	System	09 Sep 2020 21:03:56

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: MEDICATED SHAMPOOS, PRODUCT: SULFACETAMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 08:12:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 08:12:40
Data point term sent to Coder	System	09 Sep 2020 21:05:21
User entered 'Sulfacetamide wash'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:04:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 21:04:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'rosacea'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:04:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '1'	Nick Bart (b) (4)	09 Sep 2020 21:04:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Other (OTHER)'	Nick Bart (b) (4)	09 Sep 2020 21:04:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'application'	Nick Bart (b) (4)	09 Sep 2020 21:04:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'once daily (QD)'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:04:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:04:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Topical (TOPICAL)'	Nick Bart (b) (4)	09 Sep 2020 21:04:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:04:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '04 Sep 2020'	Nick Bart (b) (4)	09 Sep 2020 21:04:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4)	09 Sep 2020 21:04:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4)	09 Sep 2020 21:04:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:04:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 21:04:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 21:04:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 21:04:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 21:04:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: AGENTS FOR DERMATITIS, EXCLUDING CORTICOSTEROIDS, PRODUCT: PIMECROLIMUS, PRODUCTSYNONYM: ELIDEL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 07:16:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 07:16:34
Data point term sent to Coder	System	09 Sep 2020 21:06:23
User entered 'Elidel 1%'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:05:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'rosacea'	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '1'	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Other (OTHER)'	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'application'	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'twice daily (BID)'	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Topical (TOPICAL)'	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '04 Sep 2020'	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 21:05:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Sep 2020 21:05:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 21:05:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 21:05:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: CHEMOTHERAPEUTICS FOR TOPICAL USE, ATC: OTHER CHEMOTHERAPEUTICS, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 07:58:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 07:58:42
Data point term sent to Coder	System	09 Sep 2020 21:06:24
User entered 'metronidazole 0.75%'	Nick Bart (b) (4) (b) (4)	09 Sep 2020 21:06:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'rosacea'	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '1'	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Other (OTHER)'	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'application'	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'twice daily (BID)'	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Topical (TOPICAL)'	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '04 Sep 2020'	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered '0'	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'Yes (Y)'	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered empty.	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 19:15:11
User entered 'No (N)'	Nick Bart (b) (4)	09 Sep 2020 21:06:21
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Sep 2020 21:06:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 21:06:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 21:06:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:16
Data point term sent to Coder	System	21 Dec 2020 14:35:24
User entered 'influenza vaccine'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4) (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'Yes (Y)'	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'influenza prevention'	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered '0.5'	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'mL (mL)'	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered empty.	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'once (ONCE)'	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered empty.	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'Intramuscular (INTRAMUSCULAR)'	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered empty.	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered '26 Oct 2020'	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered '0'	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'No (N)'	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered '26 Oct 2020'	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'No (N)'	Nick Bart (b) (4)	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User entered empty.	System	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:46
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User entered empty.	System	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Sep 2020 15:46:46
	Nick Bart (b) (4)	
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:46
User entered empty.	System	21 Dec 2020 14:34:21
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:51
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Sep 2020 15:46:46
	Nick Bart (b) (4)	
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User closed query 'Per DM CLR: This Con Med had dose increased on 19 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 08:51:39
Query 'Per DM CLR: This Con Med had dose increased on 19 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'No AE of worsening Hypertension' (Site from DM).	Nick Bart (b) (4) (b) (4)	08 Feb 2021 15:02:19
User opened query 'Per DM CLR: This Con Med had dose increased on 19 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 03:27:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:16
Data point term sent to Coder	System	21 Dec 2020 14:35:24
User entered 'amlodipine'	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:34:48

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'No (N)'	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'hypertension'	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered '10'	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'mg (mg)'	Nick Bart (b) (4)	21 Dec 2020 14:34:48
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	21 Dec 2020 14:31:57
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:46:51

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered empty.	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'once daily (QD)'	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered empty.	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered empty.	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered '19 Oct 2020'	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered '0'	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'Yes (Y)'	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered empty.	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 20:37:33
User entered 'No (N)'	Nick Bart (b) (4)	21 Dec 2020 14:34:48
	(b) (4)	
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Dec 2020 14:34:48
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Dec 2020 14:34:48
DataPoint activated with code reason code Data required.	Nick Bart (b) (4) (b) (4)	21 Dec 2020 14:31:57
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4) (b) (4)	11 Sep 2020 15:46:51

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Dec 2020 14:34:48
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	21 Dec 2020 14:31:57
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:46:51

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 08:15:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:15:05
Data point term sent to Coder	System	12 Mar 2021 20:38:29
Coding entries removed.	Nick Bart (b) (4)	12 Mar 2021 20:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 09:05:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 09:05:44
Data point term sent to Coder	System	08 Feb 2021 20:17:56
User entered 'Hydrocodone'	Atanas Filev (b) (4) (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	Nick Bart (b) (4) (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4) (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered 'No (N)'	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:40:46
DataPoint Un-verified.	Nick Bart (b) (4)	12 Mar 2021 20:37:48
User entered 'post-op pain' reason for change: Data Entry Error	(b) (4) Nick Bart (b) (4)	12 Mar 2021 20:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered 'worsening of degenerative spondylolisthesis'	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:40:50
User closed query 'Per DM CLR: Please review the dose as this seems to be a dose of a combination medication. Please update the name of medication to reflect both components of the combination medication. Kindly update accordingly.	(b) (4), (b) (6)	15 Mar 2021 15:56:52
' (Site from DM).		
Query 'Per DM CLR: Please review the dose as this seems to be a dose of a combination medication. Please update the name of medication to reflect both components of the combination medication. Kindly update accordingly.	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:38:35
' answered with 'Per PI, correct as entered. Medication is a combination drug' (Site from DM).		
DataPoint Un-verified.	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:38:13
User entered '5/325' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:38:13
User opened query 'Per DM CLR: Please review the dose as this seems to be a dose of a combination medication. Please update the name of medication to reflect both components of the combination medication. Kindly update accordingly.	(b) (4), (b) (6)	10 Mar 2021 10:09:23
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered '5-325'	Atanas Filev (b) (4) (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	Nick Bart (b) (4) (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4) (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered 'mg (mg)'	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered empty.	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered 'three times daily (TID)'	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered empty.	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered 'Oral (ORAL)'	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered empty.	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered '27 Dec 2020'	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered '0'	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered 'No (N)'	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered '02 Jan 2021'	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:02:46
User entered 'No (N)'	Atanas Filev (b) (4)	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:00

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User entered '3'	System	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Sep 2020 15:47:00
	Nick Bart (b) (4)	
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User entered '1'	System	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Sep 2020 15:47:00
	Nick Bart (b) (4)	
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:49
User entered '804 (804)'	System	08 Feb 2021 20:17:28
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	27 Jan 2021 20:44:10
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Sep 2020 15:47:00
	Nick Bart (b) (4)	
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
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)	24 Mar 2021 12:00:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 12:00:48
Data point term sent to Coder Coding entries removed.	System	12 Mar 2021 20:39:38
	Nick Bart (b) (4)	12 Mar 2021 20:38:50
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)	03 Mar 2021 13:41:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 13:41:18
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:03:47
Data point term sent to Coder	System	08 Feb 2021 20:18:57
User entered 'Tylenol ES'	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 20:18:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 20:18:38
User entered 'No (N)' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	08 Feb 2021 20:18:38
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 20:18:30
User entered empty.	Atanas Filev (b) (4) (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	Nick Bart (b) (4) (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4) (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:40:36
DataPoint Un-verified.	Nick Bart (b) (4)	12 Mar 2021 20:38:50
User entered 'post-op pain' reason for change: Data Entry Error	(b) (4) Nick Bart (b) (4)	12 Mar 2021 20:38:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User entered 'Worsening of degenerative spondylolisthesis'	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User entered '500'	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User entered 'mg (mg)'	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User entered empty.	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User entered 'as needed (PRN)'	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User entered empty.	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User entered 'Oral (ORAL)'	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User entered empty.	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User entered '27 Dec 2020'	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User entered '0'	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User entered 'No (N)' reason for change: Data Entry Error	Atanas Filev (b) (4)	08 Feb 2021 20:18:38
User entered 'Yes (Y)'	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	08 Feb 2021 20:18:38
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	08 Feb 2021 20:18:30
User entered '02 Jan 2021'	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:03:47
User entered 'No (N)'	Atanas Filev (b) (4)	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	(b) (4) Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Nick Bart (b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User entered empty.	System	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Sep 2020 15:47:06
	Nick Bart (b) (4)	
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User entered empty.	System	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Sep 2020 15:47:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:58
User entered empty.	System	08 Feb 2021 20:18:30
DataPoint activated with code reason code Data required.	Nick Bart (b) (4)	27 Jan 2021 20:44:15
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Sep 2020 15:47:06
	Nick Bart (b) (4)	
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
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)	29 Mar 2021 16:12:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:12:10
Data point term sent to Coder	System	29 Mar 2021 16:10:53
User entered 'acetaminophen'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op pain'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '1000'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:45
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 12:43:24
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:43:24
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:43:24
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'once (ONCE)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User entered '2'	System	13 Apr 2021 12:43:24
User entered empty.	System	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User entered '1'	System	13 Apr 2021 12:43:24
User entered empty.	System	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:48
User entered '804 (804)'	System	13 Apr 2021 12:43:24
User entered empty.	System	29 Mar 2021 16:10:41

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
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)	29 Mar 2021 16:14:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:14:17
Data point term sent to Coder	System	29 Mar 2021 16:13:03
User entered 'acetaminophen'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op pain'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:28:15
User closed query 'Per MAR, dose is 1000g/100mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:28:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, dose is 1000g/100mL. Please reconcile.' answered with 'updated.' (Site from CRA).	Atanas Filev (b) (4)	07 Apr 2021 22:52:51
User entered '1000/100' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 22:52:12
User opened query 'Per MAR, dose is 1000g/100mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:30:50
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:30:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '1000'	Nick Bart (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:28:03
User closed query 'Per MAR, dose is 1000g/100mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:28:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, dose is 1000g/100mL. Please reconcile.' answered with 'Updated.' (Site from CRA).	Atanas Filev (b) (4)	07 Apr 2021 22:52:52
User entered 'Other (OTHER)' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 22:52:12
User opened query 'Per MAR, dose is 1000g/100mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:30:57
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:30:32
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'mg (mg)'	Nick Bart (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:28:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Un-verified.	(b) (4)	07 Apr 2021 22:52:12
User entered 'mg/mL' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 22:52:12
DataPoint Verified.	(b) (4)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User closed query 'Per MAR, given q6h.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:28:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:28:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, given q6h.' answered with 'Q6H = four times daily' (Site from CRA).	Atanas Filev (b) (4)	07 Apr 2021 22:53:03
User opened query 'Per MAR, given q6h.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:31:53
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:31:12
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'four times daily (QID)'	Nick Bart (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User entered '4'	System	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User entered '1'	System	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:52
User entered '804 (804)'	System	29 Mar 2021 16:12:21

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
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)	29 Mar 2021 16:15:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:15:07
Data point term sent to Coder	System	29 Mar 2021 16:14:04
User entered 'acetaminophen'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op pain'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '1000'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'four times daily (QID)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Oral (ORAL)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '23 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '24 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User entered '4'	System	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User entered '1'	System	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:58
User entered '804 (804)'	System	29 Mar 2021 16:13:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN SODIUM, PRODUCTSYNONYM: ANCEF [CEFAZOLIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:37:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:37:25
Data point term sent to Coder	System	29 Mar 2021 16:15:06
User entered 'cefazolin (ancef)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op prophylaxis'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:30:54
User closed query 'Per MAR, dose is 2g/100mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:30:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, dose is 2g/100mL. Please reconcile.' answered with 'Updated.' (Site from CRA).	Atanas Filev (b) (4)	07 Apr 2021 22:50:43
User entered '2/100' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 22:50:23
User opened query 'Per MAR, dose is 2g/100mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:03:50
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:03:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '2'	Nick Bart (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User closed query 'Per MAR, dose is 2g/100mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:30:58
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:30:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, dose is 2g/100mL. Please reconcile.' answered with 'Updated.' (Site from CRA).	(b) (4) Atanas Filev (b) (4)	07 Apr 2021 22:50:45
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 22:50:23
User opened query 'Per MAR, dose is 2g/100mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:03:54
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:03:33
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'g (g)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:31:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Un-verified.	(b) (4)	07 Apr 2021 22:50:23
User entered 'g/mL' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 22:50:23
DataPoint Verified.	(b) (4)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'once (ONCE)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User entered empty.	System	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User entered empty.	System	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:04
User entered empty.	System	29 Mar 2021 16:14:07

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
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: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:41:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:41:15
Data point term sent to Coder	System	29 Mar 2021 16:15:06
User entered 'dexamethasone'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op pain'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '10'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'once (ONCE)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User entered empty.	System	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User entered empty.	System	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:07
User entered empty.	System	29 Mar 2021 16:14:33

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
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: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:41:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:41:15
Data point term sent to Coder	System	29 Mar 2021 16:16:06
User entered 'dexamethasone'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op pain'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '10'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'once (ONCE)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '23 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '23 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User entered empty.	System	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User entered empty.	System	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:10
User entered empty.	System	29 Mar 2021 16:15:14

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:22
Data point term sent to Coder	System	29 Mar 2021 16:16:06
User entered 'gabapentin'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op pain'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '100'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'three times daily (TID)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Oral (ORAL)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Feb 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:31:32
User closed query 'Per MAR, given until 24Dec20. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:31:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered '24 Dec 2020' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 22:58:05
User entered '22 Dec 2020' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 22:55:53
Query 'Per MAR, given until 24Dec20. Please reconcile.' answered with 'updated.' (Site from CRA).	Atanas Filev (b) (4)	07 Apr 2021 22:53:32
User entered '24 Dec 2020' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 22:53:26
User opened query 'Per MAR, given until 24Dec20. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:07:12
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:06:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User entered '3'	System	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User entered '1'	System	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:36
User entered '804 (804)'	System	29 Mar 2021 16:15:47

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: AMINOGLYCOSIDE ANTIBACTERIALS, ATC: OTHER AMINOGLYCOSIDES, PRODUCT: GENTAMICIN, PRODUCTSYNONYM: GENTAMYCIN [GENTAMICIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:36
Data point term sent to Coder	System	29 Mar 2021 16:19:20
User entered 'gentamycin'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op prophylaxis'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:32:03
User closed query 'Per MAR, dose is 80mg/100mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:32:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, dose is 80mg/100mL. Please reconcile.' answered with 'Updated.' (Site from CRA).	Atanas Filev (b) (4)	07 Apr 2021 22:59:51
User entered '80/100' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 22:59:43
User opened query 'Per MAR, dose is 80mg/100mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:01:23
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '80'	Nick Bart (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:32:09
User closed query 'Per MAR, dose is 80mg/100mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:32:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, dose is 80mg/100mL. Please reconcile.' answered with 'Updated. ' (Site from CRA).	Atanas Filev (b) (4)	07 Apr 2021 22:59:53
User entered 'Other (OTHER)' reason for change: New Information	Atanas Filev (b) (4)	07 Apr 2021 22:59:43
User opened query 'Per MAR, dose is 80mg/100mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:01:58
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:01:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'mg (mg)'	Nick Bart (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:32:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Un-verified.	(b) (4)	07 Apr 2021 22:59:43
User entered 'mg/mL' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 22:59:43
DataPoint Verified.	(b) (4)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'once (ONCE)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User entered empty.	System	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User entered empty.	System	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:42
User entered empty.	System	29 Mar 2021 16:19:06

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:29:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:29:55
Data point term sent to Coder	System	29 Mar 2021 16:20:23
User entered 'hydromorphan (dilaudid)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op pain'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0.5'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'other (OTHER)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'every ten minutes as needed'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User entered empty.	System	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User entered empty.	System	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:20
User entered empty.	System	29 Mar 2021 16:20:03

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
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: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:22:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:22:18
Data point term sent to Coder	System	29 Mar 2021 16:21:23
User entered 'lactated ringers'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op fluids'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '125'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'mL (mL)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'other (OTHER)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'continuous'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '23 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User entered empty.	System	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User entered empty.	System	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:28
User entered empty.	System	29 Mar 2021 16:20:55

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:16:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:16:28
User signature succeeded.	Mimi Van Der Leden (b) (4)	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:24:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:24:26
Data point term sent to Coder	System	29 Mar 2021 16:21:24
User entered 'magnesium sulfate'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op pain'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:32:26
User closed query 'Per MAR, dose is 2g/50mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:32:24
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, dose is 2g/50mL. Please reconcile.' answered with 'updated.' (Site from CRA).	(b) (4)	07 Apr 2021 23:01:29
User entered '2/50' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:01:12
User opened query 'Per MAR, dose is 2g/50mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:50:52
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 18:50:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '2'	Nick Bart (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User closed query 'Per MAR, dose is 2g/50mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:32:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:32:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, dose is 2g/50mL. Please reconcile.' answered with 'updated.' (Site from CRA).	(b) (4)	07 Apr 2021 23:01:30
User entered 'Other (OTHER)' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:01:12
User opened query 'Per MAR, dose is 2g/50mL. Please reconcile.' (Site from CRA).	(b) (4)	07 Apr 2021 18:51:10
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 18:50:28
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'g (g)'	Nick Bart (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:32:31
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Un-verified.	(b) (4)	07 Apr 2021 23:01:12
User entered 'g/mL' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:01:12
DataPoint Verified.	(b) (4)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'once (ONCE)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User entered empty.	System	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User entered empty.	System	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:32
User entered empty.	System	29 Mar 2021 16:21:24

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
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)	30 Mar 2021 09:05:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 09:05:36
Data point term sent to Coder	System	29 Mar 2021 16:23:25
User entered 'ondansetron (zofran)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op nausea'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:32:48
User closed query 'Per MAR, 4mg/2mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:32:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, 4mg/2mL. Please reconcile.' answered with 'correct as is. ' (Site from CRA).	Atanas Filev (b) (4)	07 Apr 2021 23:10:59
User entered '4' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:10:46
User entered '4/2' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:05:39
User opened query 'Per MAR, 4mg/2mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:37:39
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 18:37:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '4'	Nick Bart (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User closed query 'Per MAR, 4mg/2mL. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:32:52
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:32:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, 4mg/2mL. Please reconcile.' answered with 'correct as is. ' (Site from CRA).	(b) (4)	07 Apr 2021 23:11:00
User entered 'mg (mg)' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:10:46
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 23:05:39
User opened query 'Per MAR, 4mg/2mL. Please reconcile.' (Site from CRA).	Atanas Filev (b) (4)	07 Apr 2021 18:37:44
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 18:37:12
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'mg (mg)'	Nick Bart (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:32:54
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered empty; reason for change Data Entry Error	(b) (4)	
DataPoint Un-verified.	Atanas Filev (b) (4)	07 Apr 2021 23:10:46
User entered 'mg/mL' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Atanas Filev (b) (4)	07 Apr 2021 23:05:39
	(b) (4)	
	Atanas Filev (b) (4)	07 Apr 2021 23:05:39
	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4)	29 Mar 2021 16:23:05
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:32:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Un-verified.	(b) (4)	07 Apr 2021 23:13:13
User entered 'once (ONCE)' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:13:13
DataPoint Verified.	(b) (4)	07 Apr 2021 18:34:33
User entered 'other (OTHER)'	Nick Bart (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Un-verified.	(b) (4)	07 Apr 2021 23:13:13
User entered empty; reason for change Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:13:13
DataPoint Verified.	(b) (4)	07 Apr 2021 18:40:03
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 18:39:58
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'every six hours as needed'	Nick Bart (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Intravenous (INTRAVENOUS)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User closed query 'Per MAR, given once on 23Dec20. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:33:01
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:32:59
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, given once on 23Dec20. Please reconcile.' answered with 'Updated. ' (Site from CRA).	Atanas Filev (b) (4)	07 Apr 2021 23:13:19
User entered '23 Dec 2020' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:13:13
User opened query 'Per MAR, given once on 23Dec20. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:39:40
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 18:39:10
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User closed query 'Per MAR, given once on 23Dec20. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:33:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, given once on 23Dec20. Please reconcile.' answered with 'Updated. ' (Site from CRA).	Atanas Filev (b) (4)	07 Apr 2021 23:13:23
User entered '23 Dec 2020' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:13:13
User opened query 'Per MAR, given once on 23Dec20. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:39:49
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 18:39:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '24 Dec 2020'	Nick Bart (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User entered empty.	System	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User entered empty.	System	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:49
User entered empty.	System	29 Mar 2021 16:23:05

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
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)	30 Mar 2021 09:00:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 09:00:28
Data point term sent to Coder	System	29 Mar 2021 16:24:26
User entered 'oxycodone'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'post-op pain'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '5'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'as needed (PRN)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Oral (ORAL)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User entered empty.	System	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User entered empty.	System	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:21:52
User entered empty.	System	29 Mar 2021 16:23:46

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNOSIDES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:27:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:27:17
Data point term sent to Coder	System	29 Mar 2021 16:25:27
User entered 'sennosides'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'constipation'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User closed query 'Per MAR, dose administered is 187mg' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:33:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:21
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
Query 'Per MAR, dose administered is 187mg' answered with 'updated. ' (Site from CRA).	(b) (4)	07 Apr 2021 23:19:42
User entered '17.2' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:19:37
DataPoint Un-verified.	(b) (4)	07 Apr 2021 18:34:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:34:33
User opened query 'Per MAR, dose administered is 187mg' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:29:18
User entered '86'	Nick Bart (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'mg (mg)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'once daily (QD)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'Oral (ORAL)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered empty.	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '22 Dec 2020'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered '0'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Un-verified.	(b) (4)	07 Apr 2021 23:19:37
User entered '23 Dec 2020' reason for change: Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:19:37
DataPoint Verified.	(b) (4)	07 Apr 2021 18:34:33
User entered '24 Dec 2020'	Nick Bart (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User entered '1'	System	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User entered '1'	System	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:02
User entered '804 (804)'	System	29 Mar 2021 16:24:35

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: TRANEXAMIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 09:16:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:16:52
Data point term sent to Coder	System	07 Apr 2021 23:44:56
User entered 'Tranexamic Acid (TCX)'	Atanas Filev (b) (4) (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered 'Post-Op bleeding'	(b) (4) Atanas Filev (b) (4) (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered '1000/100' reason for change: Data Entry Error	(b) (4)	
	Atanas Filev (b) (4)	07 Apr 2021 23:44:52
User entered '1000'	(b) (4)	
	Atanas Filev (b) (4)	07 Apr 2021 23:44:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Atanas Filev (b) (4)	07 Apr 2021 23:44:52
User entered 'mg (mg)'	(b) (4)	
	Atanas Filev (b) (4)	07 Apr 2021 23:44:01
	(b) (4)	

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered 'mg/mL' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 23:44:52
User entered empty.	Atanas Filev (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:27
User closed query 'Was given twice, per MAR. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:46:09
Query 'Was given twice, per MAR. Please reconcile.' answered with 'Updated ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:41:11
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 16:41:03
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 16:41:03
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 15:51:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:55
User opened query 'Was given twice, per MAR. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 15:45:55
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 15:45:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered 'once (ONCE)'	(b) (4) Atanas Filev (b) (4) (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Atanas Filev (b) (4) (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered '22 Dec 2020'	(b) (4) Atanas Filev (b) (4) (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered '0'	(b) (4) Atanas Filev (b) (4) (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered '22 Dec 2020'	(b) (4) Atanas Filev (b) (4) (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:33:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:22:34
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
User entered '2'	System	13 Apr 2021 16:41:03
User entered empty.	System	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
User entered '1'	System	13 Apr 2021 16:41:03
User entered empty.	System	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:23
User entered '804 (804)'	System	13 Apr 2021 16:41:03
User entered empty.	System	07 Apr 2021 23:44:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: BETAXOLOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 08:01:54
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 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:55
Data point term sent to Coder User entered 'BETOXALOL 0.5%'	System (b) (4), (b) (6)	13 Apr 2021 12:49:28 13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'GLAUCOMA'	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered '1'	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'g (g)'	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered '22 Dec 2020'	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered '24 Dec 2020'	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User entered '2'	System	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User entered '1'	System	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:26
User entered '804 (804)'	System	13 Apr 2021 12:49:01

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 10:46:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:46:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:55
Data point term sent to Coder	System	13 Apr 2021 12:50:28
User entered 'GABAPENTIN'	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'POST OP PAIN'	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered '300'	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered '22 Dec 2020'	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
User closed query 'Given once on 22Dec20. Stop date should be 22Dec20. please reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:49:10
Query 'Given once on 22Dec20. Stop date should be 22Dec20. please reconcile.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:40:20
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 16:40:14
User opened query 'Given once on 22Dec20. Stop date should be 22Dec20. please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 15:51:27
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 15:51:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered '23 Dec 2020'	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User entered '1'	System	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User entered '1'	System	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:32:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:32
User entered '804 (804)'	System	13 Apr 2021 12:49:52

US3952004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:32:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:52
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:43:28
User closed query 'Pre/post XRL-Spine 1 is not present in concomitant procedures page. Please add.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:43:27
Query 'Pre/post XRL-Spine 1 is not present in concomitant procedures page. Please add.' answered with 'no concomitant procedures performed outside of surgery itself' (Site from CRA).	Mimi Van Der Leden (b) (4)	25 Mar 2021 13:01:37
User opened query 'Pre/post XRL-Spine 1 is not present in concomitant procedures page. Please add.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 17:29:03
Query 'Not present.' canceled (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 17:28:12
User opened query 'Not present.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 17:28:03
User closed query 'Please add surgery, pre/post XRL-Spine 1 to concomitant procedures.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 17:28:03
Query 'Please add surgery, pre/post XRL-Spine 1 to concomitant procedures.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:42:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:42:50
User opened query 'Please add surgery, pre/post XRL-Spine 1 to concomitant procedures.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 17:48:40
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	25 Feb 2021 21:56:58

US3952004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:32:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:23:48
User entered '22 Dec 2020'	Nick Bart (b) (4)	12 Mar 2021 20:44:33
	(b) (4)	

US3952004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:32:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:23:48
User entered 'Lumbar Fusion; Lumbar laminectomy'	Nick Bart (b) (4)	12 Mar 2021 20:44:33
	(b) (4)	

US3952004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Mar 2021 14:47:44
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'updated' (Site from DM).	Mimi Van Der Leden (b) (4)	25 Mar 2021 12:59:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:23:48
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:54:56
User entered 'Adverse Event (AE)'	Nick Bart (b) (4) (b) (4)	12 Mar 2021 20:44:33

US3952004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:32:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:23:48
User entered empty.	Nick Bart (b) (4)	12 Mar 2021 20:44:33
	(b) (4)	

US3952004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:32:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:04:48
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	07 Apr 2021 19:57:09
	(b) (4), (b) (6)	
User entered '22 Dec 2020'	Mimi Van Der Leden	25 Mar 2021 13:06:14
	(b) (4)	

US3952004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:32:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:04:48
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:57:09
User entered 'XR L Spine 1 VW'	Mimi Van Der Leden (b) (4)	25 Mar 2021 13:06:14

US3952004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:32:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:04:48
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:57:09
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	25 Mar 2021 13:06:26
User entered 'Other (OTHER)' reason for change: Data Entry Error	Mimi Van Der Leden (b) (4)	25 Mar 2021 13:06:26
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	25 Mar 2021 13:06:14
User entered 'Diagnostic (DIAGNOSTIC)'	Mimi Van Der Leden (b) (4)	25 Mar 2021 13:06:14

US3952004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:32:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:04:48
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	07 Apr 2021 19:57:09
	(b) (4), (b) (6)	
User entered 'intraoperative imaging'	Mimi Van Der Leden	25 Mar 2021 13:06:14
	(b) (4)	

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered	System	09 Feb 2021 13:13:30
'USA-US215-2021-MRNA-1273-P301000002'		

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Yes (Y)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Yes (Y)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Mimi'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Van Der Leden'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered '15201 Shady Grove Dr'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Rockville'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered '20850'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 17:49:18
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:03:19
User entered 'US'	System	09 Feb 2021 13:13:55

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Mar 2021 14:50:11
User entered '3'	System	15 Mar 2021 13:20:40
User entered '2'	System	05 Mar 2021 17:48:18
User entered '1'	System	09 Feb 2021 13:13:55

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered	System	09 Feb 2021 13:13:30
'USA-US215-2021-MRNA-1273-P301000002'		

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Yes (Y)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Yes (Y)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Mimi'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Van Der Leden'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered '15201 Shady Grove Dr'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Rockville'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered '20850'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 17:49:18
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:03:19
User entered 'US'	System	09 Feb 2021 13:13:55

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Mar 2021 14:50:11
User entered '3'	System	15 Mar 2021 13:20:40
User entered '2'	System	05 Mar 2021 17:48:18
User entered '1'	System	09 Feb 2021 13:13:55

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:32:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
User entered '09/Feb/2021 13:13'	System	09 Feb 2021 13:13:55

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:32:34

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 17:49:18
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:03:19
User entered '1'	(b) (4), (b) (6)	09 Feb 2021 13:13:55

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered	System	09 Feb 2021 13:13:30
'USA-US215-2021-MRNA-1273-P301000002'		

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Yes (Y)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Yes (Y)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Mimi'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Van Der Leden'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered '15201 Shady Grove Dr'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Rockville'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered '20850'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 17:49:18
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:03:19
User entered 'US'	System	09 Feb 2021 13:13:55

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Mar 2021 14:50:11
User entered '3'	System	15 Mar 2021 13:20:40
User entered '2'	System	05 Mar 2021 17:48:18
User entered '1'	System	09 Feb 2021 13:13:55

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:32:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:21:54
User entered '05/Mar/2021 12:48'	System	05 Mar 2021 17:48:18

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:32:34

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:21:54
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 17:49:18
User entered '1'	(b) (4), (b) (6)	05 Mar 2021 17:48:18

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered	System	09 Feb 2021 13:13:30
'USA-US215-2021-MRNA-1273-P301000002'		

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Yes (Y)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Yes (Y)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Mimi'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Van Der Leden'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered '15201 Shady Grove Dr'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Rockville'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered '20850'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 17:49:18
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:03:19
User entered 'US'	System	09 Feb 2021 13:13:55

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Mar 2021 14:50:11
User entered '3'	System	15 Mar 2021 13:20:40
User entered '2'	System	05 Mar 2021 17:48:18
User entered '1'	System	09 Feb 2021 13:13:55

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:32:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:21:54
User entered '15/Mar/2021 09:20'	System	15 Mar 2021 13:20:40

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:32:34

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Mar 2021 14:49:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:21:54
User entered '1'	(b) (4), (b) (6)	15 Mar 2021 13:20:40

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered	System	09 Feb 2021 13:13:30
'USA-US215-2021-MRNA-1273-P301000002'		

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Yes (Y)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Yes (Y)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'No (N)'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Mimi'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Van Der Leden'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered '15201 Shady Grove Dr'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered 'Rockville'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 15:03:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:13:48
User entered '20850'	System	09 Feb 2021 13:13:30

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 17:49:18
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:03:19
User entered 'US'	System	09 Feb 2021 13:13:55

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:32:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Mar 2021 14:50:11
User entered '3'	System	15 Mar 2021 13:20:40
User entered '2'	System	05 Mar 2021 17:48:18
User entered '1'	System	09 Feb 2021 13:13:55

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:32:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 19:54:37
User entered '26/Mar/2021 10:50'	System	26 Mar 2021 14:50:11

US3952004

Folder: SAE USA-US215-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:32:34

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:35:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 19:54:37
User entered '1'	(b) (4), (b) (6)	26 Mar 2021 14:50:11