

US3952104 (Prod: Synexus - Optimal Research - Rockville)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:29:57

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US3952104

Form: Participant Creation

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

[Participant ID](#)

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

US3952104

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:33:08

Generated On: 10 Jun 2021 10:29:57

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 SEP 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) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

Date of Informed Consent (dd MMM yyyy)	17 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 21:33:07

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1957
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 1957
Start Year (derived)	1957
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

Condition	BROKEN LEG
Start date (dd MMM yyyy)	07 DEC 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	07 DEC 2002
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2002
Start Year (derived)	2002
Stop Month and Year (derived)	DEC 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

Condition	BILATERAL LOWER EXTREMITY EDEMA
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:33:08

Generated On: 10 Jun 2021 10:29:57

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	17 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:30 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 12:30
Height (<i>xxx.x</i>)	71.0 in
Weight (<i>xxx.x</i>)	176.0 lb
BMI (<i>xxx.x</i>)	24.59834 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 21:33:08

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

RETIRED, ALONE GROCERIES
2-3 TIMES WEEKLY, SEES
SIGNIFICANT OTHER TWICE
WEEKLY

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

PRODUCTION RELEASE (v12.003
EAB) (1725)

14 of 1979

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 21:33:08

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:33:08

Generated On: 10 Jun 2021 10:29:57

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 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) 19 Feb 2021 21:33:08

Generated On: 10 Jun 2021 10:29:57

What was the date of randomization? (dd MMM yyyy) 17 SEP 2020

What was the participant's randomization number? 191123

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 12:30
Temperature (xxx.x)	36.4 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 15:15
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:33:08

Generated On: 10 Jun 2021 10:29:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:33:08

Generated On: 10 Jun 2021 10:29:57

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 13:42 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 13:42

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:33:08

Generated On: 10 Jun 2021 10:29:57

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	17 SEP 2020
Collection time (00:00-23:59)	13:22 (24 HR)
Collection date and time (derived)	17 SEP 2020 13:22

US3952104

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 21:33:08

Generated On: 10 Jun 2021 10:29:57

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:28	17 SEP 2020 13:28
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:33:08

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐
No ☒

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

PC Time Stamp 17 SEP 2020 15:18

PC Open Date & Time 17 SEP 2020 14:02

PC Close Date & Time 17 SEP 2020 16:32

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.0 °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	17 SEP 2020 20:02
PC Open Date & Time	17 SEP 2020 17:27
PC Close Date & Time	18 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

18 SEP 2020 18:21

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

19 SEP 2020 22:56

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:29:57

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

97.2 °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

20 SEP 2020 23:50

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 21:21

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:29:57

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 12:36

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:29:57

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

98.0 °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

23 SEP 2020 21:07

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 15:10

PC Open Date & Time

17 SEP 2020 14:02

PC Close Date & Time

17 SEP 2020 16:32

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

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

17 SEP 2020 20:03

PC Open Date & Time

17 SEP 2020 17:27

PC Close Date & Time

18 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:29:57

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

18 SEP 2020 18:22

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:29:57

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

19 SEP 2020 22:57

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:29:57

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

20 SEP 2020 23:50

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:29:57

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

21 SEP 2020 21:22

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:29:57

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

22 SEP 2020 12:37

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:29:57

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

23 SEP 2020 21:07

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 15:14
PC Open Date & Time	17 SEP 2020 14:02
PC Close Date & Time	17 SEP 2020 16:32

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 20:04
PC Open Date & Time	17 SEP 2020 17:27
PC Close Date & Time	18 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

Yes ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

Yes ☐	
PC Time stamp	19 SEP 2020 22:57
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

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 ☒

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EAB) (1725)

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

Yes ☐	
PC Time stamp	20 SEP 2020 23:51
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

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 ☒

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EAB) (1725)

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

Yes ☐	
PC Time stamp	21 SEP 2020 21:22
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

Yes ☐	
PC Time stamp	22 SEP 2020 12:37
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

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

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EAB) (1725)

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

Yes ☐	
PC Time stamp	23 SEP 2020 21:08
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3952104

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952104

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:32:08

Generated On: 10 Jun 2021 10:29:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952104

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:32:08

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:32:08

Generated On: 10 Jun 2021 10:29:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952104

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:32:08

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

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

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

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

US3952104

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

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.

US3952104

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3952104

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3952104

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

Collection date (dd MMM yyyy)

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

US3952104

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:33:06

Generated On: 10 Jun 2021 10:29:57

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

US3952104

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:32:08

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:33:06

Generated On: 10 Jun 2021 10:29:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952104

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:33:06

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952104

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:33:07

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	18 NOV 2020
Time of assessment (00:00-23:59)	12:38 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 12:38
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952104

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

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.

US3952104

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	18 NOV 2020

Collection time (00:00-23:59)	12:39 (24 HR)

Collection date and time (derived)	18 NOV 2020 12:39

US3952104

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:33:09

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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 ☐

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 07:53:44
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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	29 NOV 2020 12:13:35
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

06 DEC 2020 14:55:54

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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	12 DEC 2020 18:07:41
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

29 DEC 2020 21:51:34

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

09 JAN 2021 13:02:08

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

17 JAN 2021 14:55:47

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

24 JAN 2021 23:54:02

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

30 JAN 2021 18:15:20

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

07 FEB 2021 14:02:33

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

15 FEB 2021 19:06:00

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

27 FEB 2021 21:59:14

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

06 MAR 2021 16:20:23

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

15 MAR 2021 16:21:05

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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	21 MAR 2021 13:08:42
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

28 MAR 2021 20:34:12

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

04 APR 2021 12:40:29

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

10 APR 2021 18:36:37

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

18 APR 2021 08:21:42

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

24 APR 2021 11:47:42

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

01 MAY 2021 02:01:09

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

DAY 236

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

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

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

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

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

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

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

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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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

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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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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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 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

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Please identify below 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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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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 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

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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 ☐

US3952104

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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

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09 FEB 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

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16 FEB 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

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23 FEB 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

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02 MAR 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

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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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

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Date and time of submission

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05 MAR 2022 00:01

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09 MAR 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

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16 MAR 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

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23 MAR 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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13 APR 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

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20 APR 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

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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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

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08 JUN 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

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06 JUL 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

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31 AUG 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

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07 SEP 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

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14 SEP 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

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28 SEP 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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°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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

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05 OCT 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

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26 OCT 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3952104

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:29:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 22:00:06

US3952104

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:43:42

Generated On: 10 Jun 2021 10:29:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952104

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:43:42

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952104

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:51:58

Generated On: 10 Jun 2021 10:29:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952104

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:51:58

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:51:58

Generated On: 10 Jun 2021 10:29:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952104

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:51:58

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 19:51:58

Generated On: 10 Jun 2021 10:29:57

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	01 APR 2021

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

Folder OID	VISIT4

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 19:51:58

Generated On: 10 Jun 2021 10:29:57

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	01 APR 2021
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 10:05
Temperature (xxx.x)	37.1 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952104

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 19:51:58

Generated On: 10 Jun 2021 10:29:57

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.

US3952104

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 19:51:58

Generated On: 10 Jun 2021 10:29:57

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3952104

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:51:58

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

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

US3952104

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3952104

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:29:57

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3952104

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

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	02 MAR 2021

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

Folder OID	UNBLND_DECIDE

US3952104

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Date of updated informed consent (<i>dd MMM yyyy</i>)	02 MAR 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (<i>dd MMM yyyy</i>)	02 MAR 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	1

US3952104

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Height	71 in
Weight	175 lb
BMI (xxx.x)	24.45858

US3952104

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Height	71 in
Weight	175 lb
BMI (xxx.x)	24.45858
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	04 MAR 2021
Time of assessment (00:00-23:59)	12:16 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 12:16
Temperature (xxx.x)	36 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3952104

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Height	71 in
Weight	175 lb
BMI (xxx.x)	24.45858
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	04 MAR 2021
Time of assessment (00:00-23:59)	14:08 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 14:08
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify _____	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3952104

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

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 MAR 2021

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

US3952104

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

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 04 MAR 2021

What was the treatment time? (00:00-23:59) 13:33 (24 HR)

Treatment Date and Time (derived) 04 MAR 2021 13:33

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

US3952104

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	02 MAR 2021
Collection time (00:00-23:59)	16:24 (24 HR)
Collection date and time (derived)	02 MAR 2021 16:24

US3952104

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 20:15:56

Generated On: 10 Jun 2021 10:29:57

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	04 MAR 2021
Collection time (00:00 - 23:59)	12:30
Collection Date and Time (derived)	04 MAR 2021 12:30

US3952104

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

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952104

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:51:58

Generated On: 10 Jun 2021 10:29:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952104

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:51:58

Generated On: 10 Jun 2021 10:29:57

Is the participant continuing to the next visit?	Yes ☒
	No ☐
Continuing Flag	1
OLD29 Placebo Flag	1

US3952104

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD29

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3952104

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

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.

US3952104

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 APR 2021

Collection time (00:00-23:59)

10:30 (24 HR)

Collection date and time (derived)

01 APR 2021 10:30

US3952104

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 19:10:31

Generated On: 10 Jun 2021 10:29:57

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:22:14

Generated On: 10 Jun 2021 10:29:57

AEID	USA-US215-2020-MRNA-1273-P30 1000003
Adverse event	HIP FRACTURE
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)	05 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	07 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	12 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:22:14

Generated On: 10 Jun 2021 10:29:57

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	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:22:14

Generated On: 10 Jun 2021 10:29:57

SUBJECT FELL AND
FRACTURED HIP. ADMITTED
TO HOSPITAL; DISCHARGED TO
REHAB. FURTHER DETAILS
UPON RECEIPT OF MEDICAL
RECORDS.

UPON RECEIPT OF MEDICAL
RECORD, FURTHER
INFORMATION IS AVAILABLE.
SUBJECT FELL ON 05OCT2020
AND LAY ON FLOOR UNTIL
TAKEN TO HOSPITAL ON
07OCT2020. ADMITTED TO
HOSPITAL WITH A LEFT
FEMORAL NECK FRACTURE.
HAD SURGERY 08OCT2020;
PROCEDURE WAS A LEFT
TROCHANTERIC NAILING. PT
HAD AN UNCOMPLICATED
COURSE. PT AND OT BEGAN IN
HOSPITAL. WAS DISCHARGED
TO A SNF ON 12OCT2020 FOR
CONTINUED PT. DISCHARGED
HOME ON 24OCT2020. OF NOTE,
TESTED COVID NEGATIVE IN
HOSPITAL.

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

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 19:51:57

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Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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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)	UN UNK 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 (2)

Data signed: (b) (4) 08 Apr 2021 19:51:57

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Name of Medication SUPER BETA PROSTATE

Prophylaxis Yes ☐
No ☒

Indication ENLARGED PROSTATE

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 19:51:57

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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)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 19:51:57

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Name of Medication PNEUMOVAX

Prophylaxis Yes ☒
No ☐

Indication PNEUMONIA VACCINE

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 (3)

Data signed: (b) (4) 08 Apr 2021 19:51:57

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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)	UN APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	UN APR 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 (4)

Data signed: (b) (4) 08 Apr 2021 19:51:57

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Name of Medication TYLENOL [ACETAMINOPHEN]

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE

Dose per administration 400

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

If dose unit is Other, specify ML/HOUR

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) 08 Apr 2021 19:51:57

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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)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	08 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	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 (5)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication TYLENOL [ACETAMINOPHEN]

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

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) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

	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)		09 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 11 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication CALCIUM CITRATE

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE

Dose per administration 950

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) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

	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)		09 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 12 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 (7)

Data signed: (b) (4) 08 Apr 2021 19:51:57

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Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 8 HOURS

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) 08 Apr 2021 19:51:57

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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)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
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 (8)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE

Dose per administration 2000

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 (8)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

	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)		09 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 12 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 (9)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication ENOXAPRIN [LOVENOX]

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE

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 (9)

Data signed: (b) (4) 08 Apr 2021 19:51:57

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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)	07 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	12 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 (10)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE

Dose per administration 100

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

If dose unit is Other, specify CC PER HOUR

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

	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)	07 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 08 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
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 (11)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE

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

EVERY FOUR HOURS PRN

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) 08 Apr 2021 19:51:57

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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)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	08 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
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 (12)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication ZOFRAN

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PREVENTION

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

EVERY SIX HOURS PRN

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) 08 Apr 2021 19:51:57

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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)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 08 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication MIRALAX

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PREVENTION

Dose per administration 1

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

If dose unit is Other, specify PACKET

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 12 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	☒

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication SENOKOT

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PREVENTION

Dose per administration 8.6/50

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 QHS
Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

	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)		07 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 11 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE

Dose per administration 125

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

If dose unit is Other, specify CC PER HOUR

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 (15)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

	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)	07 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		07 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 ☐	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication ELIQUIS

Prophylaxis Yes ☒
No ☐

Indication DEEP VEIN THROMBOSIS
PROPHYLAXIS

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

	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)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS/BONE HEALTH
[SECONDARY TO HIP
FRACTURE]

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	21 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Name of Medication CALCITRATE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS/BONE HEALTH
[SECONDARY TO HIP
FRACTURE]

Dose per administration 950

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
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	☒

US3952104

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3952104

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
08 OCT 2020	LEFT TROCHANTERIC NAILING	Adverse Event	
12 OCT 2020	CONTINUED PHYSICAL THERAPY FOR FRACTURED LEFT HIP	Adverse Event	

US3952104

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

Date of dosing discontinuation (dd MMM yyyy) 19 OCT 2020

Primary reason for dosing discontinuation

AE (specify)	☒
SAE (specify)	☐
Death	☐
Lost To Follow-up	☐
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☐
Due to SARS-COV-2	☐
Other	☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify #1

US3952104

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:29:57

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 ☐

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

SAEID	USA-US215-2020-MRNA-1273-P301000003
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)	5

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

SAEID	USA-US215-2020-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	20/OCT/2020 14:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

SAEID	USA-US215-2020-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	30/OCT/2020 18:16
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.	False

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

SAEID	USA-US215-2020-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	02/NOV/2020 21:31
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

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

SAEID	USA-US215-2020-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	06/NOV/2020 18:33
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

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

SAEID	USA-US215-2020-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	11/NOV/2020 15:33
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

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 08 Apr 2021 19:51:57

Generated On: 10 Jun 2021 10:29:57

SAEID	USA-US215-2020-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	25/MAR/2021 10:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3952104 (Prod: Synexus - Optimal Research - Rockville)

US3952104

Form: Participant Creation

Generated On: 10 Jun 2021 10:29:57

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'US3952104'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:34:22

US3952104

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	Nick Bart	21 Sep 2020 13:41:11

US3952104

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:34:23

US3952104

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Clinic (Clinic)'	Nick Bart (b) (4)	21 Sep 2020 13:41:11

US3952104

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'SCRN'	System	21 Sep 2020 13:41:11

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered (b) (6) 1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:34:24

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '67'	Nick Bart (b) (4)	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'YEARS'	System	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered '67'	System	17 Sep 2020 19:00:31

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Male (M)'	Nick Bart (b) (4)	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Nick Bart (b) (4)	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '1'	Nick Bart (b) (4)	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	Nick Bart	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:29:57

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart (b) (4)	21 Sep 2020 13:44:49

US3952104

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:29:57

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '17 Sep 2020'	Brianne Okunji (b) (4)	17 Sep 2020 19:00:31

US3952104

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:29:57

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'Sep 2020'	System	17 Sep 2020 19:00:31

US3952104

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:29:57

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered '2020'	System	17 Sep 2020 19:00:31

US3952104

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:29:57

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Amendment 3 (3)'	Brianne Okunji (b) (4)	17 Sep 2020 19:00:31

US3952104

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:29:57

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	Brianne Okunji (b) (4)	17 Sep 2020 19:00:31

US3952104

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:29:57

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	Brianne Okunji (b) (4)	17 Sep 2020 19:00:31

US3952104

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:29:57

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	Brianne Okunji (b) (4)	17 Sep 2020 19:00:31

US3952104

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:29:57

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	Brianne Okunji (b) (4)	17 Sep 2020 19:00:31

US3952104

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:29:57

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:34:23

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:29:57

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered '1'	System	17 Sep 2020 19:01:16

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:29:57

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	Brianne Okunji (b) (4)	17 Sep 2020 19:01:16

US3952104

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:29:57

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	Nick Bart	21 Sep 2020 13:48:33

US3952104

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:29:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 05:23:37
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Subject reported no medications for this indication' (Site from DM).	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:40:15
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 18:00:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 13:50:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 13:50:39
Data point term sent to Coder	System	21 Sep 2020 13:49:52
User entered 'asthma'	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:49:10

US3952104

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:29:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'un UNK 1957'	Nick Bart	21 Sep 2020 13:49:10

US3952104

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:49:10

US3952104

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:29:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	Nick Bart	21 Sep 2020 13:49:10

US3952104

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:29:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:49:10

US3952104

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:29:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:49:10

US3952104

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:29:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'Jan 1957'	System	21 Sep 2020 13:49:10

US3952104

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:29:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered '1957'	System	21 Sep 2020 13:49:10

US3952104

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:29:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered empty.	System	21 Sep 2020 13:49:10

US3952104

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:29:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered empty.	System	21 Sep 2020 13:49:10

US3952104

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:29:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Per MM: Please specify the type of allergen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:10:24
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)	05 Nov 2020 19:48:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:48:46
Data point term sent to Coder	System	05 Nov 2020 19:47:35
Query 'Per MM: Please specify the type of allergen. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:46:56
User closed query 'DM-Coding: The verbatim allergies cannot be referenced as reported. Please clarify this clinical event with more details if it is animal allergy, drug allergy, seasonal allergy, food allergy, etc. and amend /update the term accordingly in the diagnosis field to enable coding.' (Site from System).	System	05 Nov 2020 19:46:53
Query 'DM-Coding: The verbatim allergies cannot be referenced as reported. Please clarify this clinical event with more details if it is animal allergy, drug allergy, seasonal allergy, food allergy, etc. and amend /update the term accordingly in the diagnosis field to enable coding.' answered with 'updated' (Site from System).	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:46:53
User entered 'seasonal ALLERGIES' reason for change: Per Query Resolution	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:46:47
User opened query 'Per MM: Please specify the type of allergen. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 08:00:11
User opened query 'DM-Coding: The verbatim allergies cannot be referenced as reported. Please clarify this clinical event with more details if it is animal allergy, drug allergy, seasonal allergy, food allergy, etc. and amend /update the term accordingly in the diagnosis field to enable coding.' (Site from System).	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:50:44

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EAB) (1725)

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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:29:57

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	21 Sep 2020 13:49:54
User entered 'allergies'	Nick Bart (b) (4)	21 Sep 2020 13:49:21
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:29:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'un UNK 2020'	Nick Bart (b) (4)	21 Sep 2020 13:49:21

US3952104

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart (b) (4)	21 Sep 2020 13:49:21

US3952104

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:29:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	Nick Bart	21 Sep 2020 13:49:21

US3952104

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:29:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:49:21

US3952104

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:29:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:49:21

US3952104

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:29:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'Jan 2020'	System	21 Sep 2020 13:49:21

US3952104

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:29:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered '2020'	System	21 Sep 2020 13:49:21

US3952104

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:29:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered empty.	System	21 Sep 2020 13:49:21

US3952104

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:29:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered empty.	System	21 Sep 2020 13:49:21

US3952104

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:29:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 13:50:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 13:50:39
Data point term sent to Coder	System	21 Sep 2020 13:49:52
User entered 'enlarged prostate'	Nick Bart (b) (4)	21 Sep 2020 13:49:35

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:29:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'un UNK 2014'	Nick Bart	21 Sep 2020 13:49:35

US3952104

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart (b) (4)	21 Sep 2020 13:49:35

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:29:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	Nick Bart	21 Sep 2020 13:49:35

US3952104

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:29:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:49:35

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:29:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:49:35

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:29:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'Jan 2014'	System	21 Sep 2020 13:49:35

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:29:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered '2014'	System	21 Sep 2020 13:49:35

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:29:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered empty.	System	21 Sep 2020 13:49:35

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:29:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered empty.	System	21 Sep 2020 13:49:35

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:29:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Lower limb fracture, LLT: Broken leg - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 13:51:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 13:51:45
Data point term sent to Coder	System	21 Sep 2020 13:50:55
User entered 'broken leg'	Nick Bart (b) (4)	21 Sep 2020 13:49:55

US3952104

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:29:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '07 Dec 2002'	Nick Bart (b) (4)	21 Sep 2020 13:49:55

US3952104

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:49:55

US3952104

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:29:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	Nick Bart	21 Sep 2020 13:49:55

US3952104

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:29:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '07 Dec 2002'	Nick Bart (b) (4)	21 Sep 2020 13:49:55

US3952104

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:29:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart (b) (4)	21 Sep 2020 13:49:55

US3952104

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:29:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'Dec 2002'	System	21 Sep 2020 13:49:55

US3952104

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:29:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered '2002'	System	21 Sep 2020 13:49:55

US3952104

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:29:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'Dec 2002'	System	21 Sep 2020 13:49:55

US3952104

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:29:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered '2002'	System	21 Sep 2020 13:49:55

US3952104

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:29:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 13:51:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 13:51:44
Data point term sent to Coder	System	21 Sep 2020 13:50:55
User entered 'bilateral lower extremity edema'	Nick Bart (b) (4)	21 Sep 2020 13:50:13

US3952104

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:29:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'un UNK 2019'	Nick Bart	21 Sep 2020 13:50:13

US3952104

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:50:13

US3952104

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:29:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	Nick Bart	21 Sep 2020 13:50:13

US3952104

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:29:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:50:13

US3952104

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:29:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:50:13

US3952104

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:29:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'Jan 2019'	System	21 Sep 2020 13:50:13

US3952104

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:29:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered '2019'	System	21 Sep 2020 13:50:13

US3952104

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:29:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered empty.	System	21 Sep 2020 13:50:13

US3952104

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:29:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered empty.	System	21 Sep 2020 13:50:13

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	Nick Bart	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '17 Sep 2020'	Nick Bart (b) (4)	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '12:30'	Nick Bart (b) (4)	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered '17 Sep 2020 12:30'	System	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '71.0' in	Nick Bart	21 Sep 2020 13:48:14
DataPoint set to visible.	System	17 Sep 2020 19:01:16

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '176.0' lb	Nick Bart	21 Sep 2020 13:48:14
DataPoint set to visible.	System	17 Sep 2020 19:01:16

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered '24.59834'	System	21 Sep 2020 13:48:14
DataPoint set to visible.	System	17 Sep 2020 19:01:16

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'kg/m2'	System	21 Sep 2020 13:48:14
DataPoint set to visible.	System	17 Sep 2020 19:01:16

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure should be recorded as 'ND' at Screening.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:10:35
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure should be recorded as 'ND' at Screening.' answered with 'updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:36:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:36:14
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure should be recorded as 'ND' at Screening.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 16:21:00
User entered '36.4' C	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	05 Nov 2020 19:36:14
User entered 'Oral (Oral)'	Nick Bart (b) (4)	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	Nick Bart	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Nov 2020 19:36:14
User entered '60'	Nick Bart (b) (4)	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'bpm'	System	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Nov 2020 19:36:14
User entered '12'	Nick Bart (b) (4)	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'breaths/min'	System	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Nov 2020 19:36:14
User entered '120'	Nick Bart (b) (4)	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'mmHg'	System	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Nov 2020 19:36:14
User entered '70'	Nick Bart (b) (4)	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User entered 'mmHg'	System	21 Sep 2020 13:48:14

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 18:32:29

US3952104

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29

US3952104

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:48:29

US3952104

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '17 Sep 2020'	Nick Bart (b) (4)	21 Sep 2020 13:48:29

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Sep 2020 13:46:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 13:46:27
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 13:46:10
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Sep 2020 13:46:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 13:46:27
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 13:46:10
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Sep 2020 13:46:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 13:46:27
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 13:46:10
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Sep 2020 13:46:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 13:46:27
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 13:46:10
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Sep 2020 13:46:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 13:46:27
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 13:46:10
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Sep 2020 13:46:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 13:46:27
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 13:46:10
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Sep 2020 13:46:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 13:46:27
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 13:46:10
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Sep 2020 13:46:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 13:46:27
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 13:46:10
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Sep 2020 13:46:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 13:46:27
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 13:46:10
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Sep 2020 13:46:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 13:46:27
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 13:46:10
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	21 Sep 2020 13:46:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 13:46:27
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 13:46:10
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	Nick Bart (b) (4)	21 Sep 2020 13:46:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'retired, alone groceries 2-3 times weekly, sees significant other twice weekly'	Nick Bart (b) (4)	21 Sep 2020 13:46:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:46:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '1'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:46:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '0'	Nick Bart (b) (4)	21 Sep 2020 13:46:10

US3952104

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:29:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	Nick Bart	21 Sep 2020 13:46:10

US3952104

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:50:30

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '17 Sep 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:50:30

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:50:30

US3952104

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered 'VISIT1'	System	21 Sep 2020 13:50:30

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 17:14:20

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:29:57

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '191123'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 17:14:20

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:29:57

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 17:14:20

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:29:57

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	Nick Bart	21 Sep 2020 13:51:01

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:29:57

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	Nick Bart	21 Sep 2020 13:51:01

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:29:57

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:51:01

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:29:57

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:51:01

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:29:57

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4)	21 Sep 2020 13:51:01
	Nick Bart (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:29:57

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	21 Sep 2020 13:51:01
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 09:25:49
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:25:49

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:10:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:36:38
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' answered with 'updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:36:33
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 16:20:08
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Nov 2020 19:36:38
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:10:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:36:38
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' answered with 'updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:36:33
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 16:20:08
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Nov 2020 19:36:38
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Pre-Dose Vital Signs should be recorded at Visit 1 Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:10:54
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Pre-Dose Vital Signs should be recorded at Visit 1 Day 1. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:38:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:37:59
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Pre-Dose Vital Signs should be recorded at Visit 1 Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 16:20:23
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '17 Sep 2020' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 19:37:59
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:52:17
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '12:30' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 19:37:59
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:52:17
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered '17 Sep 2020 12:30'	System	05 Nov 2020 19:37:59
User entered empty.	System	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '36.4' C reason for change: Data Entry	(b) (4)	05 Nov 2020 19:37:59
Error	Nick Bart (b) (4)	21 Sep 2020 13:52:17
User entered empty.	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 19:37:59
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:52:17
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4)	21 Sep 2020 13:52:17
	Nick Bart (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '60' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 19:37:59
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered 'bpm'	System	05 Nov 2020 19:37:59
User entered empty.	System	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '12' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 19:37:59
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:52:17
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered 'breaths/min'	System	05 Nov 2020 19:37:59
User entered empty.	System	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '120' reason for change: Data Entry Error	Nick Bart (b) (4)	05 Nov 2020 19:37:59
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered 'mmHg'	System	05 Nov 2020 19:37:59
User entered empty.	System	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '70' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 19:37:59
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered 'mmHg'	System	05 Nov 2020 19:37:59
User entered empty.	System	21 Sep 2020 13:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:10:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:36:38
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' answered with 'updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:36:33
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 16:20:08
User entered empty.	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Nov 2020 19:36:38
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '17 Sep 2020'	(b) (4)	21 Sep 2020 13:52:17
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '15:15'	(b) (4)	21 Sep 2020 13:52:17
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered '17 Sep 2020 15:15'	System	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '36.6' C	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '77'	(b) (4)	21 Sep 2020 13:52:17
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered 'bpm'	System	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '16'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered 'breaths/min'	System	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '126'	(b) (4)	21 Sep 2020 13:52:17
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered 'mmHg'	System	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '71'	(b) (4)	21 Sep 2020 13:52:17
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered 'mmHg'	System	21 Sep 2020 13:52:17

US3952104

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4)	21 Sep 2020 13:52:26
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4)	21 Sep 2020 13:52:26
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	17 Sep 2020 19:02:15

US3952104

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	17 Sep 2020 19:02:15

US3952104

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	Brianne Okunji (b) (4)	17 Sep 2020 19:02:15

US3952104

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 19:02:15

US3952104

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '17 Sep 2020'	(b) (4) Brianne Okunji (b) (4) (b) (4)	17 Sep 2020 19:02:15

US3952104

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '13:42'	Brianne Okunji (b) (4)	17 Sep 2020 19:02:15

US3952104

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered '17 Sep 2020 13:42'	System	17 Sep 2020 19:02:15

US3952104

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	17 Sep 2020 19:02:15

US3952104

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered 'ONCE'	System	17 Sep 2020 19:02:15

US3952104

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 19:02:15

US3952104

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:51:14

US3952104

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '17 Sep 2020'	(b) (4)	
	Nick Bart (b) (4)	21 Sep 2020 13:51:14
	(b) (4)	

US3952104

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '13:22'	(b) (4)	21 Sep 2020 13:51:14
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered '17 Sep 2020 13:22'	System	21 Sep 2020 13:51:14

US3952104

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:29:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '17 Sep 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:51:28

US3952104

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:29:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:51:28

US3952104

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:29:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:51:28

US3952104

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:29:57

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '13:28'	(b) (4)	21 Sep 2020 13:51:28
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:29:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered '17 Sep 2020 13:28'	System	21 Sep 2020 13:51:28

US3952104

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:29:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:51:28

US3952104

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:29:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4)	21 Sep 2020 13:51:28
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:29:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4)	21 Sep 2020 13:51:28
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:29:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered empty.	System	21 Sep 2020 13:51:28

US3952104

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:51:32

US3952104

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered '1'	System	21 Sep 2020 13:51:32

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:17:59', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '3f956ac5-480f-4a92-b4d8-8fcdad00d16e' User entered 'Yes (Y)'	System	17 Sep 2020 19:18:53
	System	17 Sep 2020 19:18:53

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:18:33', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '3f956ac5-480f-4a92-b4d8-8fcdad00d16e' User entered '97.8'	System	17 Sep 2020 19:18:53
	System	17 Sep 2020 19:18:53

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:18:39', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '3f956ac5-480f-4a92-b4d8-8fcdad00d16e' User entered 'No (N)'	System	17 Sep 2020 19:18:53
	System	17 Sep 2020 19:18:53

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:18:51', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '3f956ac5-480f-4a92-b4d8-8fcdad00d16e' User entered '17 Sep 2020 15:18'	System	17 Sep 2020 19:18:53
	System	17 Sep 2020 19:18:53

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '17 Sep 2020 14:02'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '17 Sep 2020 16:32'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:02:23', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '007ee893-4666-46f1-a668-5699c9cb78f8'	System	18 Sep 2020 00:02:56
User entered 'Yes (Y)'	System	18 Sep 2020 00:02:56

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:02:36', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '007ee893-4666-46f1-a668-5699c9cb78f8' User entered '96.0'	System	18 Sep 2020 00:02:56
	System	18 Sep 2020 00:02:56

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:02:42', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '007ee893-4666-46f1-a668-5699c9cb78f8'	System	18 Sep 2020 00:02:56
User entered 'No (N)'	System	18 Sep 2020 00:02:56

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:02:51', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '007ee893-4666-46f1-a668-5699c9cb78f8' User entered '17 Sep 2020 20:02'	System	18 Sep 2020 00:02:56
	System	18 Sep 2020 00:02:56

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '17 Sep 2020 17:27'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 2'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:29:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-18T18:21:13', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'cdba993f-700e-4926-a043-dcf6975a4c50'	System	18 Sep 2020 22:21:39
User entered 'Yes (Y)'	System	18 Sep 2020 22:21:39

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:29:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-18T18:21:23', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'cdba993f-700e-4926-a043-dcf6975a4c50' User entered '97.9'	System	18 Sep 2020 22:21:39
	System	18 Sep 2020 22:21:39

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-18T18:21:32', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'cdba993f-700e-4926-a043-dcf6975a4c50'	System	18 Sep 2020 22:21:39
User entered 'No (N)'	System	18 Sep 2020 22:21:39

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-18T18:21:38', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'cdba993f-700e-4926-a043-dcf6975a4c50'	System	18 Sep 2020 22:21:39
User entered '18 Sep 2020 18:21'	System	18 Sep 2020 22:21:39

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 3'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:29:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:56:02', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'fc81ea95-b80f-45de-b880-94132cae70fb' User entered 'Yes (Y)'	System	20 Sep 2020 02:56:43
	System	20 Sep 2020 02:56:43

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:29:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:56:12', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'fc81ea95-b80f-45de-b880-94132cae70fb' User entered '97.9'	System	20 Sep 2020 02:56:43
	System	20 Sep 2020 02:56:43

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:56:18', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'fc81ea95-b80f-45de-b880-94132cae70fb' User entered 'No (N)'	System	20 Sep 2020 02:56:43
	System	20 Sep 2020 02:56:43

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:56:39', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'fc81ea95-b80f-45de-b880-94132cae70fb' User entered '19 Sep 2020 22:56'	System	20 Sep 2020 02:56:43
	System	20 Sep 2020 02:56:43

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 4'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:29:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:49:36', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '49285d53-e8de-4959-a930-f8c58ba489c9' User entered 'Yes (Y)'	System	21 Sep 2020 03:50:14
	System	21 Sep 2020 03:50:14

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:29:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:49:48', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '49285d53-e8de-4959-a930-f8c58ba489c9' User entered '97.2'	System	21 Sep 2020 03:50:14
	System	21 Sep 2020 03:50:14

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:49:59', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '49285d53-e8de-4959-a930-f8c58ba489c9'	System	21 Sep 2020 03:50:14
User entered 'No (N)'	System	21 Sep 2020 03:50:14

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:50:11', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '49285d53-e8de-4959-a930-f8c58ba489c9' User entered '20 Sep 2020 23:50'	System	21 Sep 2020 03:50:14
	System	21 Sep 2020 03:50:14

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 5'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:29:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:21:16', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '0d39c04c-772a-47d0-9498-656173796929' User entered 'Yes (Y)'	System	22 Sep 2020 01:21:40
	System	22 Sep 2020 01:21:40

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:29:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:21:28', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '0d39c04c-772a-47d0-9498-656173796929' User entered '97.6'	System	22 Sep 2020 01:21:40
	System	22 Sep 2020 01:21:40

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:21:33', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '0d39c04c-772a-47d0-9498-656173796929' User entered 'No (N)'	System	22 Sep 2020 01:21:40
	System	22 Sep 2020 01:21:40

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:21:38', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '0d39c04c-772a-47d0-9498-656173796929' User entered '21 Sep 2020 21:21'	System	22 Sep 2020 01:21:40
	System	22 Sep 2020 01:21:40

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 6'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:29:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:36:18', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'bd818048-6e68-407d-af0f-388f344a8259' User entered 'Yes (Y)'	System	22 Sep 2020 16:36:46
	System	22 Sep 2020 16:36:46

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:29:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:36:26', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'bd818048-6e68-407d-af0f-388f344a8259' User entered '96.4'	System	22 Sep 2020 16:36:46
	System	22 Sep 2020 16:36:46

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:36:32', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'bd818048-6e68-407d-af0f-388f344a8259'	System	22 Sep 2020 16:36:46
User entered 'No (N)'	System	22 Sep 2020 16:36:46

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:36:42', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'bd818048-6e68-407d-af0f-388f344a8259'	System	22 Sep 2020 16:36:46
User entered '22 Sep 2020 12:36'	System	22 Sep 2020 16:36:46

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 7'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:29:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:06:31', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f660052d-4875-47fe-9e2d-1b633bf14b91' User entered 'Yes (Y)'	System	24 Sep 2020 01:07:14
	System	24 Sep 2020 01:07:14

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:29:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:06:53', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f660052d-4875-47fe-9e2d-1b633bf14b91' User entered '98.0'	System	24 Sep 2020 01:07:14
	System	24 Sep 2020 01:07:14

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:06:59', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f660052d-4875-47fe-9e2d-1b633bf14b91'	System	24 Sep 2020 01:07:14
User entered 'No (N)'	System	24 Sep 2020 01:07:14

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:07:10', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f660052d-4875-47fe-9e2d-1b633bf14b91' User entered '23 Sep 2020 21:07'	System	24 Sep 2020 01:07:14
	System	24 Sep 2020 01:07:14

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:09:40', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f8a60999-8220-4692-8240-d88688ca5498'	System	17 Sep 2020 19:10:33
User entered 'None (1)'	System	17 Sep 2020 19:10:33

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:09:47', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f8a60999-8220-4692-8240-d88688ca5498' User entered 'No (N)'	System	17 Sep 2020 19:10:33
	System	17 Sep 2020 19:10:33

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:09:53', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f8a60999-8220-4692-8240-d88688ca5498' User entered 'No (N)'	System	17 Sep 2020 19:10:33
	System	17 Sep 2020 19:10:33

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:09:59', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f8a60999-8220-4692-8240-d88688ca5498'	System	17 Sep 2020 19:10:33
User entered 'None (1)'	System	17 Sep 2020 19:10:33

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:10:29', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f8a60999-8220-4692-8240-d88688ca5498'	System	17 Sep 2020 19:10:33
User entered '17 Sep 2020 15:10'	System	17 Sep 2020 19:10:33

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '17 Sep 2020 14:02'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '17 Sep 2020 16:32'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:03:02', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '5aaed678-e4f7-4042-90fd-21d93dd5c3a6'	System	18 Sep 2020 00:03:39
User entered 'None (1)'	System	18 Sep 2020 00:03:39

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:03:06', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '5aaed678-e4f7-4042-90fd-21d93dd5c3a6' User entered 'No (N)'	System	18 Sep 2020 00:03:39
	System	18 Sep 2020 00:03:39

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:03:10', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '5aaed678-e4f7-4042-90fd-21d93dd5c3a6' User entered 'No (N)'	System	18 Sep 2020 00:03:39
	System	18 Sep 2020 00:03:39

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:03:26', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '5aaed678-e4f7-4042-90fd-21d93dd5c3a6' User entered 'None (1)'	System	18 Sep 2020 00:03:39
	System	18 Sep 2020 00:03:39

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:03:34', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '5aaed678-e4f7-4042-90fd-21d93dd5c3a6' User entered '17 Sep 2020 20:03'	System	18 Sep 2020 00:03:39
	System	18 Sep 2020 00:03:39

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '17 Sep 2020 17:27'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 2'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-18T18:21:48', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'e8c08ae2-4df4-4f54-9074-555ed445a709'	System	18 Sep 2020 22:22:28
User entered 'None (1)'	System	18 Sep 2020 22:22:28

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:29:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-18T18:21:52', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'e8c08ae2-4df4-4f54-9074-555ed445a709' User entered 'No (N)'	System	18 Sep 2020 22:22:28
	System	18 Sep 2020 22:22:28

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-18T18:21:59', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'e8c08ae2-4df4-4f54-9074-555ed445a709' User entered 'No (N)'	System	18 Sep 2020 22:22:28
	System	18 Sep 2020 22:22:28

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-18T18:22:05', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'e8c08ae2-4df4-4f54-9074-555ed445a709'	System	18 Sep 2020 22:22:28
User entered 'None (1)'	System	18 Sep 2020 22:22:28

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-18T18:22:23', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'e8c08ae2-4df4-4f54-9074-555ed445a709' User entered '18 Sep 2020 18:22'	System	18 Sep 2020 22:22:28
	System	18 Sep 2020 22:22:28

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 3'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:56:46', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '3d0ec39d-9ad8-451a-9a91-c508b961d753' User entered 'None (1)'	System	20 Sep 2020 02:57:15
	System	20 Sep 2020 02:57:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:29:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:56:50', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '3d0ec39d-9ad8-451a-9a91-c508b961d753'	System	20 Sep 2020 02:57:15
User entered 'No (N)'	System	20 Sep 2020 02:57:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:56:55', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '3d0ec39d-9ad8-451a-9a91-c508b961d753'	System	20 Sep 2020 02:57:15
User entered 'No (N)'	System	20 Sep 2020 02:57:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:56:59', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '3d0ec39d-9ad8-451a-9a91-c508b961d753' User entered 'None (1)'	System	20 Sep 2020 02:57:15
	System	20 Sep 2020 02:57:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:57:11', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '3d0ec39d-9ad8-451a-9a91-c508b961d753' User entered '19 Sep 2020 22:57'	System	20 Sep 2020 02:57:15
	System	20 Sep 2020 02:57:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 4'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:50:23', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7ff0c954-abc5-4bae-90ef-f490606827a0' User entered 'None (1)'	System	21 Sep 2020 03:51:04
	System	21 Sep 2020 03:51:04

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:29:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:50:28', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7ff0c954-abc5-4bae-90ef-f490606827a0' User entered 'No (N)'	System	21 Sep 2020 03:51:04
	System	21 Sep 2020 03:51:04

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:50:35', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7ff0c954-abc5-4bae-90ef-f490606827a0' User entered 'No (N)'	System	21 Sep 2020 03:51:04
	System	21 Sep 2020 03:51:04

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:50:43', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7ff0c954-abc5-4bae-90ef-f490606827a0'	System	21 Sep 2020 03:51:04
User entered 'None (1)'	System	21 Sep 2020 03:51:04

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:50:59', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7ff0c954-abc5-4bae-90ef-f490606827a0'	System	21 Sep 2020 03:51:04
User entered '20 Sep 2020 23:50'	System	21 Sep 2020 03:51:04

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 5'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:21:43', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '82751b67-d186-4126-8de1-7a6a5fe337ab' User entered 'None (1)'	System	22 Sep 2020 01:22:05
	System	22 Sep 2020 01:22:05

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:29:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:21:48', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '82751b67-d186-4126-8de1-7a6a5fe337ab' User entered 'No (N)'	System	22 Sep 2020 01:22:05
	System	22 Sep 2020 01:22:05

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:21:53', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '82751b67-d186-4126-8de1-7a6a5fe337ab' User entered 'No (N)'	System	22 Sep 2020 01:22:05
	System	22 Sep 2020 01:22:05

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:21:56', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '82751b67-d186-4126-8de1-7a6a5fe337ab' User entered 'None (1)'	System	22 Sep 2020 01:22:05
	System	22 Sep 2020 01:22:05

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:22:01', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '82751b67-d186-4126-8de1-7a6a5fe337ab' User entered '21 Sep 2020 21:22'	System	22 Sep 2020 01:22:05
	System	22 Sep 2020 01:22:05

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 6'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:36:48', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7f50801a-69c2-4f13-9a23-70deccc696cd' User entered 'None (1)'	System	22 Sep 2020 16:37:13
	System	22 Sep 2020 16:37:13

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:29:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:36:53', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7f50801a-69c2-4f13-9a23-70deccc696cd' User entered 'No (N)'	System	22 Sep 2020 16:37:13
	System	22 Sep 2020 16:37:13

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:36:59', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7f50801a-69c2-4f13-9a23-70deccc696cd' User entered 'No (N)'	System	22 Sep 2020 16:37:13
	System	22 Sep 2020 16:37:13

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:37:04', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7f50801a-69c2-4f13-9a23-70deccc696cd' User entered 'None (1)'	System	22 Sep 2020 16:37:13
	System	22 Sep 2020 16:37:13

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:37:10', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7f50801a-69c2-4f13-9a23-70deccc696cd' User entered '22 Sep 2020 12:37'	System	22 Sep 2020 16:37:13
	System	22 Sep 2020 16:37:13

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 7'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:07:16', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '92475077-ad70-4367-aa5f-e08aa2fbe66a' User entered 'None (1)'	System	24 Sep 2020 01:07:41
	System	24 Sep 2020 01:07:41

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:29:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:07:21', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '92475077-ad70-4367-aa5f-e08aa2fbe66a' User entered 'No (N)'	System	24 Sep 2020 01:07:41
	System	24 Sep 2020 01:07:41

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:07:25', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '92475077-ad70-4367-aa5f-e08aa2fbe66a' User entered 'No (N)'	System	24 Sep 2020 01:07:41
	System	24 Sep 2020 01:07:41

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:29:57

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 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:07:30', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '92475077-ad70-4367-aa5f-e08aa2fbe66a' User entered 'None (1)'	System	24 Sep 2020 01:07:41
	System	24 Sep 2020 01:07:41

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:29:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:07:39', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '92475077-ad70-4367-aa5f-e08aa2fbe66a' User entered '23 Sep 2020 21:07'	System	24 Sep 2020 01:07:41
	System	24 Sep 2020 01:07:41

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:57
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:13:43', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '332fd68a-f9ac-4bf4-ad8f-9dd94718ac59' User entered 'None (0)'	System	17 Sep 2020 19:14:41
	System	17 Sep 2020 19:14:41

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:13:48', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '332fd68a-f9ac-4bf4-ad8f-9dd94718ac59' User entered 'None (0)'	System	17 Sep 2020 19:14:41
	System	17 Sep 2020 19:14:41

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:13:53', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '332fd68a-f9ac-4bf4-ad8f-9dd94718ac59' User entered 'None (0)'	System	17 Sep 2020 19:14:41
	System	17 Sep 2020 19:14:41

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:13:59', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '332fd68a-f9ac-4bf4-ad8f-9dd94718ac59' User entered 'None (0)'	System	17 Sep 2020 19:14:41
	System	17 Sep 2020 19:14:41

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:14:04', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '332fd68a-f9ac-4bf4-ad8f-9dd94718ac59' User entered 'None (0)'	System	17 Sep 2020 19:14:41
	System	17 Sep 2020 19:14:41

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:14:07', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '332fd68a-f9ac-4bf4-ad8f-9dd94718ac59' User entered 'None (0)'	System	17 Sep 2020 19:14:41
	System	17 Sep 2020 19:14:41

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

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 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:14:18', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '332fd68a-f9ac-4bf4-ad8f-9dd94718ac59' User entered 'No (N)'	System	17 Sep 2020 19:14:41
	System	17 Sep 2020 19:14:41

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T15:14:38', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '332fd68a-f9ac-4bf4-ad8f-9dd94718ac59' User entered '17 Sep 2020 15:14'	System	17 Sep 2020 19:14:41
	System	17 Sep 2020 19:14:41

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '17 Sep 2020 14:02'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '17 Sep 2020 16:32'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:03:45', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '022ca616-02c5-4d15-b0f4-bf332adbe058' User entered 'None (0)'	System	18 Sep 2020 00:04:27
	System	18 Sep 2020 00:04:27

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:03:50', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '022ca616-02c5-4d15-b0f4-bf332adbe058' User entered 'None (0)'	System	18 Sep 2020 00:04:27
	System	18 Sep 2020 00:04:27

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:03:54', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '022ca616-02c5-4d15-b0f4-bf332adbe058' User entered 'None (0)'	System	18 Sep 2020 00:04:27
	System	18 Sep 2020 00:04:27

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:03:57', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '022ca616-02c5-4d15-b0f4-bf332adbe058' User entered 'None (0)'	System	18 Sep 2020 00:04:27
	System	18 Sep 2020 00:04:27

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '022ca616-02c5-4d15-b0f4-bf332adbe058' User entered 'None (0)'	System	18 Sep 2020 00:04:27
	System	18 Sep 2020 00:04:27

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:04:03', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '022ca616-02c5-4d15-b0f4-bf332adbe058' User entered 'None (0)'	System	18 Sep 2020 00:04:27
	System	18 Sep 2020 00:04:27

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

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 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:04:10', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '022ca616-02c5-4d15-b0f4-bf332adbe058' User entered 'No (N)'	System	18 Sep 2020 00:04:27
	System	18 Sep 2020 00:04:27

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-17T20:04:24', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '022ca616-02c5-4d15-b0f4-bf332adbe058' User entered '17 Sep 2020 20:04'	System	18 Sep 2020 00:04:27
	System	18 Sep 2020 00:04:27

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '17 Sep 2020 17:27'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 2'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:17:51

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:17:51

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:17:51

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:17:51

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

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) [REDACTED]	26 Feb 2021 02:17:51

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:17:51

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 3'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:57:20', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '228c97e1-0e34-415b-a4a7-16dea3ad4119' User entered 'None (0)'	System	20 Sep 2020 02:57:53
	System	20 Sep 2020 02:57:53

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:57:23', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '228c97e1-0e34-415b-a4a7-16dea3ad4119' User entered 'None (0)'	System	20 Sep 2020 02:57:53
	System	20 Sep 2020 02:57:53

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:57:27', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '228c97e1-0e34-415b-a4a7-16dea3ad4119' User entered 'None (0)'	System	20 Sep 2020 02:57:53
	System	20 Sep 2020 02:57:53

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:57:32', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '228c97e1-0e34-415b-a4a7-16dea3ad4119' User entered 'None (0)'	System	20 Sep 2020 02:57:53
	System	20 Sep 2020 02:57:53

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:57:36', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '228c97e1-0e34-415b-a4a7-16dea3ad4119' User entered 'None (0)'	System	20 Sep 2020 02:57:53
	System	20 Sep 2020 02:57:53

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:57:39', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '228c97e1-0e34-415b-a4a7-16dea3ad4119' User entered 'None (0)'	System	20 Sep 2020 02:57:53
	System	20 Sep 2020 02:57:53

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

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 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:57:44', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '228c97e1-0e34-415b-a4a7-16dea3ad4119' User entered 'No (N)'	System	20 Sep 2020 02:57:53
	System	20 Sep 2020 02:57:53

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-19T22:57:51', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '228c97e1-0e34-415b-a4a7-16dea3ad4119' User entered '19 Sep 2020 22:57'	System	20 Sep 2020 02:57:53
	System	20 Sep 2020 02:57:53

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 4'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:51:12', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'ec937725-7ebc-4556-9b9d-cb540c1e8067' User entered 'None (0)'	System	21 Sep 2020 03:52:01
	System	21 Sep 2020 03:52:01

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:51:17', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'ec937725-7ebc-4556-9b9d-cb540c1e8067' User entered 'None (0)'	System	21 Sep 2020 03:52:01
	System	21 Sep 2020 03:52:01

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:51:22', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'ec937725-7ebc-4556-9b9d-cb540c1e8067' User entered 'None (0)'	System	21 Sep 2020 03:52:01
	System	21 Sep 2020 03:52:01

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:51:29', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'ec937725-7ebc-4556-9b9d-cb540c1e8067' User entered 'None (0)'	System	21 Sep 2020 03:52:01
	System	21 Sep 2020 03:52:01

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:51:33', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'ec937725-7ebc-4556-9b9d-cb540c1e8067' User entered 'None (0)'	System	21 Sep 2020 03:52:01
	System	21 Sep 2020 03:52:01

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:51:37', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'ec937725-7ebc-4556-9b9d-cb540c1e8067' User entered 'None (0)'	System	21 Sep 2020 03:52:01
	System	21 Sep 2020 03:52:01

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

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 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:51:45', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'ec937725-7ebc-4556-9b9d-cb540c1e8067' User entered 'No (N)'	System	21 Sep 2020 03:52:01
	System	21 Sep 2020 03:52:01

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-20T23:51:59', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'ec937725-7ebc-4556-9b9d-cb540c1e8067' User entered '20 Sep 2020 23:51'	System	21 Sep 2020 03:52:01
	System	21 Sep 2020 03:52:01

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 5'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:22:10', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '66028450-2709-4094-82f8-f8fef7cf6169' User entered 'None (0)'	System	22 Sep 2020 01:22:45
	System	22 Sep 2020 01:22:45

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:22:15', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '66028450-2709-4094-82f8-f8fef7cf6169' User entered 'None (0)'	System	22 Sep 2020 01:22:45
	System	22 Sep 2020 01:22:45

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:22:19', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '66028450-2709-4094-82f8-f8fef7cf6169' User entered 'None (0)'	System	22 Sep 2020 01:22:45
	System	22 Sep 2020 01:22:45

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:22:22', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '66028450-2709-4094-82f8-f8fef7cf6169' User entered 'None (0)'	System	22 Sep 2020 01:22:45
	System	22 Sep 2020 01:22:45

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:22:25', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '66028450-2709-4094-82f8-f8fef7cf6169' User entered 'None (0)'	System	22 Sep 2020 01:22:45
	System	22 Sep 2020 01:22:45

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:22:28', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '66028450-2709-4094-82f8-f8fef7cf6169' User entered 'None (0)'	System	22 Sep 2020 01:22:45
	System	22 Sep 2020 01:22:45

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

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 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:22:31', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '66028450-2709-4094-82f8-f8fef7cf6169' User entered 'No (N)'	System	22 Sep 2020 01:22:45
	System	22 Sep 2020 01:22:45

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-21T21:22:43', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '66028450-2709-4094-82f8-f8fef7cf6169' User entered '21 Sep 2020 21:22'	System	22 Sep 2020 01:22:45
	System	22 Sep 2020 01:22:45

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 6'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:37:18', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '10a4b38d-8c28-49ca-b22b-0d7087268beb' User entered 'None (0)'	System	22 Sep 2020 16:37:54
	System	22 Sep 2020 16:37:54

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:37:21', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '10a4b38d-8c28-49ca-b22b-0d7087268beb' User entered 'None (0)'	System	22 Sep 2020 16:37:54
	System	22 Sep 2020 16:37:54

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:37:24', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '10a4b38d-8c28-49ca-b22b-0d7087268beb' User entered 'None (0)'	System	22 Sep 2020 16:37:54
	System	22 Sep 2020 16:37:54

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:37:28', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '10a4b38d-8c28-49ca-b22b-0d7087268beb' User entered 'None (0)'	System	22 Sep 2020 16:37:54
	System	22 Sep 2020 16:37:54

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:37:32', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '10a4b38d-8c28-49ca-b22b-0d7087268beb' User entered 'None (0)'	System	22 Sep 2020 16:37:54
	System	22 Sep 2020 16:37:54

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:37:35', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '10a4b38d-8c28-49ca-b22b-0d7087268beb' User entered 'None (0)'	System	22 Sep 2020 16:37:54
	System	22 Sep 2020 16:37:54

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

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 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:37:39', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '10a4b38d-8c28-49ca-b22b-0d7087268beb' User entered 'No (N)'	System	22 Sep 2020 16:37:54
	System	22 Sep 2020 16:37:54

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-22T12:37:48', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '10a4b38d-8c28-49ca-b22b-0d7087268beb' User entered '22 Sep 2020 12:37'	System	22 Sep 2020 16:37:54
	System	22 Sep 2020 16:37:54

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 7'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:07:46', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '8f0265e7-0d07-438a-b9ff-c64f51fe28f9' User entered 'None (0)'	System	24 Sep 2020 01:08:22
	System	24 Sep 2020 01:08:22

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:07:49', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '8f0265e7-0d07-438a-b9ff-c64f51fe28f9' User entered 'None (0)'	System	24 Sep 2020 01:08:22
	System	24 Sep 2020 01:08:22

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:07:53', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '8f0265e7-0d07-438a-b9ff-c64f51fe28f9' User entered 'None (0)'	System	24 Sep 2020 01:08:22
	System	24 Sep 2020 01:08:22

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:07:58', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '8f0265e7-0d07-438a-b9ff-c64f51fe28f9' User entered 'None (0)'	System	24 Sep 2020 01:08:22
	System	24 Sep 2020 01:08:22

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:08:01', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '8f0265e7-0d07-438a-b9ff-c64f51fe28f9' User entered 'None (0)'	System	24 Sep 2020 01:08:22
	System	24 Sep 2020 01:08:22

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:08:04', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '8f0265e7-0d07-438a-b9ff-c64f51fe28f9' User entered 'None (0)'	System	24 Sep 2020 01:08:22
	System	24 Sep 2020 01:08:22

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

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 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:08:10', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '8f0265e7-0d07-438a-b9ff-c64f51fe28f9'	System	24 Sep 2020 01:08:22
User entered 'No (N)'	System	24 Sep 2020 01:08:22

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-09-23T21:08:19', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '8f0265e7-0d07-438a-b9ff-c64f51fe28f9'	System	24 Sep 2020 01:08:22
User entered '23 Sep 2020 21:08'	System	24 Sep 2020 01:08:22

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 19:02:15

US3952104

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:29:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:17:51
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	01 Oct 2020 20:41:48

US3952104

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '24 Sep 2020'	Stephanie Melton (b) (4)	01 Oct 2020 20:41:48

US3952104

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	01 Oct 2020 20:41:48

US3952104

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	Stephanie Melton (b) (4)	01 Oct 2020 20:41:48

US3952104

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	01 Oct 2020 20:41:52

US3952104

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered '1'	System	01 Oct 2020 20:41:52

US3952104

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:32:08
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	01 Oct 2020 20:42:04

US3952104

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:32:08
User entered '1 Oct 2020'	Stephanie Melton (b) (4)	01 Oct 2020 20:42:04

US3952104

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:32:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	01 Oct 2020 20:42:04

US3952104

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:32:08
User entered empty.	Stephanie Melton (b) (4)	01 Oct 2020 20:42:04

US3952104

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:32:08
User entered 'Yes (Y)'	(b) (4) Stephanie Melton (b) (4)	01 Oct 2020 20:42:10

US3952104

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:26:28
User entered '1'	System	01 Oct 2020 20:42:10

US3952104

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:32:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:25:47

US3952104

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:32:08
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 11:40:15
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Correct, visit OOW' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 16:25:56
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Oct 2020 16:25:47
User entered '19 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 16:25:47

US3952104

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:32:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:25:47

US3952104

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:32:08
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:25:47

US3952104

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:32:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:26:12

US3952104

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:01:34
User entered '1'	System	21 Oct 2020 16:26:12

US3952104

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4)	03 Nov 2020 20:20:58
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:20:58

US3952104

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[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 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:20:58

US3952104

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered 'VISIT2'	System	03 Nov 2020 20:20:58

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User accepted default value 'Pre-Dose (PREDOSE)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User accepted default value 'Post-Dose (POSTDOSE)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:01

US3952104

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:06

US3952104

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:06

US3952104

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4)	02 Dec 2020 17:47:37
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4) Nick Bart (b) (4) (b) (4)	02 Dec 2020 17:47:37

US3952104

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

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 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	Nick Bart	02 Dec 2020 17:47:37

US3952104

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	02 Dec 2020 17:47:37

US3952104

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4)	02 Dec 2020 17:47:37
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	02 Dec 2020 17:47:37

US3952104

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	02 Dec 2020 17:47:37

US3952104

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	02 Dec 2020 17:47:37

US3952104

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	02 Dec 2020 17:47:37

US3952104

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	02 Dec 2020 17:47:37

US3952104

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:11

US3952104

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:11

US3952104

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:11

US3952104

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:11

US3952104

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:29:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4)	13 Jan 2021 16:46:16

US3952104

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:29:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:16

US3952104

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:29:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:16

US3952104

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:29:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:16

US3952104

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:29:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:16

US3952104

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:29:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:16

US3952104

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:29:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:16

US3952104

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:29:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	13 Jan 2021 16:46:16

US3952104

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:29:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered empty.	System	13 Jan 2021 16:46:16

US3952104

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:21:06

US3952104

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered '1'	System	03 Nov 2020 20:21:06

US3952104

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4)	03 Nov 2020 20:22:02
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:22:02

US3952104

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4)	03 Nov 2020 20:22:02
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4)	03 Nov 2020 20:22:02
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:32:08
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:22:06

US3952104

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered '1'	System	03 Nov 2020 20:22:06

US3952104

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:32:56

US3952104

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '05 Nov 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:32:56

US3952104

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:32:56

US3952104

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4)	05 Nov 2020 19:32:56
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Nov 2020 19:33:01

US3952104

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered '1'	System	05 Nov 2020 19:33:01

US3952104

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4) System	11 Dec 2020 00:19:45
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	11 Dec 2020 00:19:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 00:19:40
User entered 'No (N)'	Nick Bart (b) (4)	24 Nov 2020 13:19:38

US3952104

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '6 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Dec 2020 00:19:40
User entered empty.	Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:19:38

US3952104

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	11 Dec 2020 00:19:45
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered empty.	Nick Bart (b) (4)	24 Nov 2020 13:19:38
	(b) (4)	

US3952104

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4)	24 Nov 2020 13:19:38
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:19:42

US3952104

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered '1'	System	24 Nov 2020 13:19:42

US3952104

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:19:52

US3952104

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '18 Nov 2020'	(b) (4)	
	Nick Bart (b) (4)	24 Nov 2020 13:19:52
	(b) (4)	

US3952104

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[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 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:19:52

US3952104

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered 'VISIT3'	System	24 Nov 2020 13:19:52

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4)	24 Nov 2020 13:20:27
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '18 Nov 2020'	(b) (4)	
	Nick Bart (b) (4)	24 Nov 2020 13:20:27
	(b) (4)	

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '12:38'	(b) (4)	24 Nov 2020 13:20:27
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered '18 Nov 2020 12:38'	System	24 Nov 2020 13:20:27

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '36.8' C	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:20:27

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:20:27

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4)	24 Nov 2020 13:20:27
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '73'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:20:27

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered 'bpm'	System	24 Nov 2020 13:20:27

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User closed query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 12:33:37
Query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	22 Dec 2020 15:58:00
User opened query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 08:40:15
User entered '20'	Nick Bart (b) (4)	24 Nov 2020 13:20:27

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered 'breaths/min'	System	24 Nov 2020 13:20:27

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '123'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:20:27

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered 'mmHg'	System	24 Nov 2020 13:20:27

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '80'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:20:27

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered 'mmHg'	System	24 Nov 2020 13:20:27

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20

US3952104

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20

US3952104

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'No (N)'	(b) (4)	24 Nov 2020 13:20:09
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered empty.	(b) (4)	24 Nov 2020 13:20:09
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:20:39

US3952104

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '18 Nov 2020'	(b) (4)	24 Nov 2020 13:20:39
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered '12:39'	(b) (4)	24 Nov 2020 13:20:39
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered '18 Nov 2020 12:39'	System	24 Nov 2020 13:20:39

US3952104

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:33:09
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:19:56

US3952104

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered '1'	System	24 Nov 2020 13:19:56

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00
Data entry locked.	System	17 Sep 2020 19:02:15
User entered 'Day 64'	System	17 Sep 2020 19:02:15

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00
Data entry locked.	System	17 Sep 2020 19:02:15
User entered '17 Nov 2020 00:01'	System	17 Sep 2020 19:02:15

US3952104

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:00
Data entry locked.	System	17 Sep 2020 19:02:15
User entered '21 Nov 2020 23:59'	System	17 Sep 2020 19:02:15

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-11-23T07:53:04', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '715a8820-cc28-45b4-bb86-fc156ed13673'	System	23 Nov 2020 12:53:47
User entered 'No (N)'	System	23 Nov 2020 12:53:47

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-11-23T07:53:15', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '715a8820-cc28-45b4-bb86-fc156ed13673'	System	23 Nov 2020 12:53:47
User entered 'No (N)'	System	23 Nov 2020 12:53:47

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-11-23T07:53:44', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '715a8820-cc28-45b4-bb86-fc156ed13673' User entered '23 Nov 2020 07:53:44'	System	23 Nov 2020 12:53:47
	System	23 Nov 2020 12:53:47

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-11-29T12:13:02', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '97166859-aa3b-4249-a8cb-c54a969916a8'	System	29 Nov 2020 17:13:39
User entered 'No (N)'	System	29 Nov 2020 17:13:39

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-11-29T12:13:10', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '97166859-aa3b-4249-a8cb-c54a969916a8'	System	29 Nov 2020 17:13:39
User entered 'No (N)'	System	29 Nov 2020 17:13:39

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-11-29T12:13:35', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '97166859-aa3b-4249-a8cb-c54a969916a8' User entered '29 Nov 2020 12:13:35'	System	29 Nov 2020 17:13:39
	System	29 Nov 2020 17:13:39

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-12-06T14:55:37', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'fe004db7-7cdd-4c3f-ba01-f3570afd7484'	System	06 Dec 2020 19:55:58
User entered 'No (N)'	System	06 Dec 2020 19:55:58

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-12-06T14:55:45', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'fe004db7-7cdd-4c3f-ba01-f3570afd7484'	System	06 Dec 2020 19:55:58
User entered 'No (N)'	System	06 Dec 2020 19:55:58

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-12-06T14:55:54', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'fe004db7-7cdd-4c3f-ba01-f3570afd7484' User entered '06 Dec 2020 14:55:54'	System	06 Dec 2020 19:55:58
	System	06 Dec 2020 19:55:58

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-12-12T18:07:25', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'b5418f8d-9232-46f1-ab85-404f1c4c97d4'	System	12 Dec 2020 23:07:46
User entered 'No (N)'	System	12 Dec 2020 23:07:46

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-12-12T18:07:31', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'b5418f8d-9232-46f1-ab85-404f1c4c97d4'	System	12 Dec 2020 23:07:46
User entered 'No (N)'	System	12 Dec 2020 23:07:46

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-12-12T18:07:41', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'b5418f8d-9232-46f1-ab85-404f1c4c97d4' User entered '12 Dec 2020 18:07:41'	System	12 Dec 2020 23:07:46
	System	12 Dec 2020 23:07:46

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-12-29T21:51:25', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '5d335de4-1145-4979-b332-63fcab379f61' User entered 'No (N)'	System	30 Dec 2020 02:51:37
	System	30 Dec 2020 02:51:37

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-12-29T21:51:30', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '5d335de4-1145-4979-b332-63fcab379f61'	System	30 Dec 2020 02:51:37
User entered 'No (N)'	System	30 Dec 2020 02:51:37

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2020-12-29T21:51:34', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '5d335de4-1145-4979-b332-63fcab379f61' User entered '29 Dec 2020 21:51:34'	System	30 Dec 2020 02:51:37
	System	30 Dec 2020 02:51:37

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-01-09T13:01:53', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '74a72305-c301-4fe2-9930-045e0a598ac9' User entered 'No (N)'	System	09 Jan 2021 18:02:11
	System	09 Jan 2021 18:02:11

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-01-09T13:02:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '74a72305-c301-4fe2-9930-045e0a598ac9'	System	09 Jan 2021 18:02:11
User entered 'No (N)'	System	09 Jan 2021 18:02:11

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-01-09T13:02:08', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '74a72305-c301-4fe2-9930-045e0a598ac9' User entered '09 Jan 2021 13:02:08'	System	09 Jan 2021 18:02:11
	System	09 Jan 2021 18:02:11

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-01-17T14:55:13', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f285a054-6eb2-48e0-a075-fed4a46ea8f5'	System	17 Jan 2021 19:55:49
User entered 'No (N)'	System	17 Jan 2021 19:55:49

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-01-17T14:55:19', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f285a054-6eb2-48e0-a075-fed4a46ea8f5'	System	17 Jan 2021 19:55:49
User entered 'No (N)'	System	17 Jan 2021 19:55:49

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-01-17T14:55:47', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f285a054-6eb2-48e0-a075-fed4a46ea8f5' User entered '17 Jan 2021 14:55:47'	System	17 Jan 2021 19:55:49

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-01-24T23:53:29', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'c7677b15-00ab-4bbe-aaff-e3e926b56050'	System	25 Jan 2021 04:54:04
User entered 'No (N)'	System	25 Jan 2021 04:54:04

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-01-24T23:53:42', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'c7677b15-00ab-4bbe-aaff-e3e926b56050'	System	25 Jan 2021 04:54:04
User entered 'No (N)'	System	25 Jan 2021 04:54:04

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-01-24T23:54:02', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'c7677b15-00ab-4bbe-aaff-e3e926b56050' User entered '24 Jan 2021 23:54:02'	System	25 Jan 2021 04:54:04

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-01-30T18:15:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '404dafd2-57e4-4c86-b67b-dcf21eb600ed'	System	30 Jan 2021 23:15:23
User entered 'No (N)'	System	30 Jan 2021 23:15:23

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-01-30T18:15:15', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '404dafd2-57e4-4c86-b67b-dcf21eb600ed'	System	30 Jan 2021 23:15:23
User entered 'No (N)'	System	30 Jan 2021 23:15:23

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-01-30T18:15:20', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '404dafd2-57e4-4c86-b67b-dcf21eb600ed' User entered '30 Jan 2021 18:15:20'	System	30 Jan 2021 23:15:23
	System	30 Jan 2021 23:15:23

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-02-07T14:02:07', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'a2af335c-e81e-47ee-ad3a-33b085aba3d4'	System	07 Feb 2021 19:02:35
User entered 'No (N)'	System	07 Feb 2021 19:02:35

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-02-07T14:02:15', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'a2af335c-e81e-47ee-ad3a-33b085aba3d4'	System	07 Feb 2021 19:02:35
User entered 'No (N)'	System	07 Feb 2021 19:02:35

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-02-07T14:02:33', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'a2af335c-e81e-47ee-ad3a-33b085aba3d4'	System	07 Feb 2021 19:02:35
User entered '07 Feb 2021 14:02:33'	System	07 Feb 2021 19:02:35

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-02-15T19:05:44', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '4b4a9053-9247-435d-8e35-d2877df3a434'	System	16 Feb 2021 00:10:27
User entered 'No (N)'	System	16 Feb 2021 00:10:27

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-02-15T19:05:49', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '4b4a9053-9247-435d-8e35-d2877df3a434'	System	16 Feb 2021 00:10:27
User entered 'No (N)'	System	16 Feb 2021 00:10:27

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-02-15T19:06:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '4b4a9053-9247-435d-8e35-d2877df3a434'	System	16 Feb 2021 00:10:27
User entered '15 Feb 2021 19:06:00'	System	16 Feb 2021 00:10:27

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-02-27T16:58:50-05:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '42b09818-607d-4d8d-8d94-4c0f27c93b22'	System	27 Feb 2021 21:59:17
User entered 'No (N)'	System	27 Feb 2021 21:59:17

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-02-27T16:59:01-05:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '42b09818-607d-4d8d-8d94-4c0f27c93b22'	System	27 Feb 2021 21:59:17
User entered 'No (N)'	System	27 Feb 2021 21:59:17

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-02-27T16:59:14-05:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '42b09818-607d-4d8d-8d94-4c0f27c93b22'	System	27 Feb 2021 21:59:17
User entered '27 Feb 2021 21:59:14'	System	27 Feb 2021 21:59:17

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-03-06T16:20:10-05:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f09182b7-938e-49e9-8017-11db0027ef7d'	System	06 Mar 2021 21:20:27
User entered 'No (N)'	System	06 Mar 2021 21:20:27

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-03-06T16:20:18-05:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f09182b7-938e-49e9-8017-11db0027ef7d'	System	06 Mar 2021 21:20:27
User entered 'No (N)'	System	06 Mar 2021 21:20:27

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-03-06T16:20:23-05:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'f09182b7-938e-49e9-8017-11db0027ef7d' User entered '06 Mar 2021 16:20:23'	System	06 Mar 2021 21:20:27
	System	06 Mar 2021 21:20:27

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-03-15T16:20:47-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '120b9075-9b11-4186-aa8c-a81ebe3661db'	System	15 Mar 2021 20:21:10
User entered 'No (N)'	System	15 Mar 2021 20:21:10

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-03-15T16:20:53-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '120b9075-9b11-4186-aa8c-a81ebe3661db'	System	15 Mar 2021 20:21:10
User entered 'No (N)'	System	15 Mar 2021 20:21:10

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-03-15T16:21:05-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '120b9075-9b11-4186-aa8c-a81ebe3661db'	System	15 Mar 2021 20:21:10
User entered '15 Mar 2021 16:21:05'	System	15 Mar 2021 20:21:10

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-03-21T13:08:34-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '9613f1c7-721d-42d6-b113-3db218938b33'	System	21 Mar 2021 17:10:09
User entered 'No (N)'	System	21 Mar 2021 17:10:09

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-03-21T13:08:37-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '9613f1c7-721d-42d6-b113-3db218938b33'	System	21 Mar 2021 17:10:09
User entered 'No (N)'	System	21 Mar 2021 17:10:09

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-03-21T13:08:42-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '9613f1c7-721d-42d6-b113-3db218938b33'	System	21 Mar 2021 17:10:09
User entered '21 Mar 2021 13:08:42'	System	21 Mar 2021 17:10:09

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-03-28T20:34:02-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'e69be41c-28c2-4c60-b1e0-109d6d331b50'	System	29 Mar 2021 00:34:14
User entered 'No (N)'	System	29 Mar 2021 00:34:14

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-03-28T20:34:06-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'e69be41c-28c2-4c60-b1e0-109d6d331b50'	System	29 Mar 2021 00:34:14
User entered 'No (N)'	System	29 Mar 2021 00:34:14

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-03-28T20:34:12-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'e69be41c-28c2-4c60-b1e0-109d6d331b50'	System	29 Mar 2021 00:34:14
User entered '28 Mar 2021 20:34:12'	System	29 Mar 2021 00:34:14

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-04-04T12:40:14-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '0eae2720-f85f-466a-b06a-cc97c67ec51d'	System	04 Apr 2021 16:40:36
User entered 'No (N)'	System	04 Apr 2021 16:40:36

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-04-04T12:40:18-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '0eae2720-f85f-466a-b06a-cc97c67ec51d'	System	04 Apr 2021 16:40:36
User entered 'No (N)'	System	04 Apr 2021 16:40:36

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-04-04T12:40:29-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '0eae2720-f85f-466a-b06a-cc97c67ec51d'	System	04 Apr 2021 16:40:36
User entered '04 Apr 2021 12:40:29'	System	04 Apr 2021 16:40:36

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-04-10T18:36:26-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'cd5e8922-006f-4888-a092-df3c298e3039'	System	10 Apr 2021 22:36:40
User entered 'No (N)'	System	10 Apr 2021 22:36:40

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-04-10T18:36:31-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'cd5e8922-006f-4888-a092-df3c298e3039'	System	10 Apr 2021 22:36:40
User entered 'No (N)'	System	10 Apr 2021 22:36:40

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-04-10T18:36:37-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: 'cd5e8922-006f-4888-a092-df3c298e3039'	System	10 Apr 2021 22:36:40
User entered '10 Apr 2021 18:36:37'	System	10 Apr 2021 22:36:40

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-04-18T08:21:18-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '28cf7ec9-cdb8-45a0-8603-23d2fb7594f6'	System	18 Apr 2021 12:21:44
User entered 'No (N)'	System	18 Apr 2021 12:21:44

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-04-18T08:21:26-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '28cf7ec9-cdb8-45a0-8603-23d2fb7594f6'	System	18 Apr 2021 12:21:44
User entered 'No (N)'	System	18 Apr 2021 12:21:44

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-04-18T08:21:42-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '28cf7ec9-cdb8-45a0-8603-23d2fb7594f6'	System	18 Apr 2021 12:21:44
User entered '18 Apr 2021 08:21:42'	System	18 Apr 2021 12:21:44

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-04-24T11:47:29-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7341b9ab-570e-4e4c-81e1-425791344ab3'	System	24 Apr 2021 15:47:47
User entered 'No (N)'	System	24 Apr 2021 15:47:47

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-04-24T11:47:36-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7341b9ab-570e-4e4c-81e1-425791344ab3'	System	24 Apr 2021 15:47:47
User entered 'No (N)'	System	24 Apr 2021 15:47:47

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-04-24T11:47:42-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '7341b9ab-570e-4e4c-81e1-425791344ab3'	System	24 Apr 2021 15:47:47
User entered '24 Apr 2021 11:47:42'	System	24 Apr 2021 15:47:47

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-05-01T02:00:59-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '9afcd9f4-7bdf-4b85-941e-b2155ec644d3'	System	01 May 2021 06:01:12
User entered 'No (N)'	System	01 May 2021 06:01:12

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Have you been exposed to someone with 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 (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-05-01T02:01:04-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '9afcd9f4-7bdf-4b85-941e-b2155ec644d3'	System	01 May 2021 06:01:12
User entered 'No (N)'	System	01 May 2021 06:01:12

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-05-01T02:01:09-04:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '9afcd9f4-7bdf-4b85-941e-b2155ec644d3'	System	01 May 2021 06:01:12
User entered '01 May 2021 02:01:09'	System	01 May 2021 06:01:12

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 09:16:00

US3952104

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:29:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:00
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 09:16:00

US3952104

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:29:57

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 07:54:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-02-27T16:59:54-05:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '847c5d37-d989-44af-957e-0956cb88afc2'	System	27 Feb 2021 22:00:09
User entered 'No (N)'	System	27 Feb 2021 22:00:09

US3952104

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:29:57

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:54:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CEB357D9-A0A0-40C7-922B-EB041FC8766C)', Time: '2021-02-27T17:00:06-05:00', User OID: 'PatientReportedOutcome (US3952104)', ODM File OID: '847c5d37-d989-44af-957e-0956cb88afc2'	System	27 Feb 2021 22:00:09
User entered '27 Feb 2021 22:00:06'	System	27 Feb 2021 22:00:09

US3952104

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 00:20:08

US3952104

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:43:42
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 00:20:08

US3952104

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:43:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 00:20:08

US3952104

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 00:20:08

US3952104

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 00:20:12

US3952104

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:20
User entered '1'	System	11 Dec 2020 00:20:12

US3952104

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:52:03

US3952104

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:52:03

US3952104

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:52:03

US3952104

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:52:03

US3952104

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:52:10

US3952104

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User entered '1'	System	12 Jan 2021 22:52:10

US3952104

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	10 Feb 2021 14:54:00

US3952104

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '10 Feb 2021'	Stephanie Melton (b) (4)	10 Feb 2021 14:54:00

US3952104

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	10 Feb 2021 14:54:00

US3952104

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	Stephanie Melton (b) (4)	10 Feb 2021 14:54:00

US3952104

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	10 Feb 2021 14:54:04

US3952104

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User entered '1'	System	10 Feb 2021 14:54:04

US3952104

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:31:29

US3952104

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:31:29

US3952104

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:31:29

US3952104

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:31:29

US3952104

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:31:34

US3952104

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:59:57
User entered '1'	System	12 Mar 2021 14:31:34

US3952104

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:11:31

US3952104

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '01 Apr 2021'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:11:31

US3952104

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:11:31

US3952104

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User entered 'VISIT4'	System	05 Apr 2021 19:11:31

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:11:58

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '01 Apr 2021'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:11:58

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '10:05'	(b) (4)	05 Apr 2021 19:11:58
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User entered '01 Apr 2021 10:05'	System	05 Apr 2021 19:11:58

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '37.1' C	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:11:58

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:11:58

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	05 Apr 2021 19:11:58
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '72'	(b) (4)	05 Apr 2021 19:11:58
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User entered 'bpm'	System	05 Apr 2021 19:11:58

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '16'	Nick Bart	05 Apr 2021 19:11:58

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User entered 'breaths/min'	System	05 Apr 2021 19:11:58

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '128'	Nick Bart	05 Apr 2021 19:11:58

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User entered 'mmHg'	System	05 Apr 2021 19:11:58

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '81'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:11:58

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User entered 'mmHg'	System	05 Apr 2021 19:11:58

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 12:23:02

US3952104

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 12:23:02

US3952104

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:12:07
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	05 Apr 2021 19:12:07
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:12:54

US3952104

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:12:54

US3952104

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:12:54

US3952104

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User entered empty.	System	05 Apr 2021 19:12:54

US3952104

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:11:34

US3952104

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:23:02
User entered '1'	System	05 Apr 2021 19:11:34

US3952104

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

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:35:01

US3952104

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

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Per GCL Lab Reconciliation: Swab Sample: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in PPD Central lab, however the swab collection details are missing in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 05:56:22
Query 'Per GCL Lab Reconciliation: Swab Sample: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in PPD Central lab, however the swab collection details are missing in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Else clarify, thank you.'	(b) (4), (b) (6)	24 Mar 2021 13:35:32
answered with 'updated' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Swab Sample: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in PPD Central lab, however the swab collection details are missing in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:16:28
User entered '02 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 14:36:56
User entered '04 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 14:35:01

US3952104

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

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[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 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:35:01

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

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered 'UNBLND_DECIDE'	System	12 Mar 2021 14:35:01

US3952104

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

Form: Unblinding

Generated On: 10 Jun 2021 10:29:57

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '02 Mar 2021'	(b) (4)	(b) (4), (b) (6)

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

Form: Unblinding

Generated On: 10 Jun 2021 10:29:57

[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 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:36:12

US3952104

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

Form: Unblinding

Generated On: 10 Jun 2021 10:29:57

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:36:12

US3952104

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

Form: Unblinding

Generated On: 10 Jun 2021 10:29:57

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:36:12

US3952104

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

Form: Unblinding

Generated On: 10 Jun 2021 10:29:57

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:36:12

US3952104

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

Form: Unblinding

Generated On: 10 Jun 2021 10:29:57

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:36:12

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

Form: Unblinding

Generated On: 10 Jun 2021 10:29:57

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:36:12

US3952104

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

Form: Unblinding

Generated On: 10 Jun 2021 10:29:57

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:36:12

US3952104

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

Form: Unblinding

Generated On: 10 Jun 2021 10:29:57

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:36:12

US3952104

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

Form: Unblinding

Generated On: 10 Jun 2021 10:29:57

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered empty.	System	12 Mar 2021 14:36:12

US3952104

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

Form: Unblinding

Generated On: 10 Jun 2021 10:29:57

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered '1'	System	12 Mar 2021 14:36:12

US3952104

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	24 Mar 2021 13:41:37
User entered '71' in reason for change: Data Entry Error	System	24 Mar 2021 13:41:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 14:39:15
User entered '71' (non-conformant).	System	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '175' lb	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered '24.45858'	System	24 Mar 2021 13:41:37
User entered empty.	System	12 Mar 2021 14:39:15
DataPoint set to visible.	System	12 Mar 2021 14:36:12

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	24 Mar 2021 13:41:37
User entered '71' in reason for change: Data Entry Error	System	24 Mar 2021 13:41:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 14:39:15
User entered '71' (non-conformant).	System	12 Mar 2021 14:39:15

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '175' lb	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered '24.45858'	System	24 Mar 2021 13:41:37
User entered empty.	System	12 Mar 2021 14:39:15
DataPoint set to visible.	System	12 Mar 2021 14:36:12

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '12:16'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered '04 Mar 2021 12:16'	System	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '36' C	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '82'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered 'bpm'	System	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '16'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered 'breaths/min'	System	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '133'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered 'mmHg'	System	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '76'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:29:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered 'mmHg'	System	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	24 Mar 2021 13:41:37
User entered '71' in reason for change: Data Entry Error	System	24 Mar 2021 13:41:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 14:39:15
User entered '71' (non-conformant).	System	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '175' lb	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:29:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered '24.45858'	System	24 Mar 2021 13:41:37
User entered empty.	System	12 Mar 2021 14:39:15
DataPoint set to visible.	System	12 Mar 2021 14:36:12

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '14:08'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered '04 Mar 2021 14:08'	System	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '85'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered 'bpm'	System	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '14'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered 'breaths/min'	System	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '128'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered 'mmHg'	System	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '83'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:15

US3952104

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:29:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered 'mmHg'	System	12 Mar 2021 14:39:15

US3952104

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

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:34:52

US3952104

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

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:34:52

US3952104

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

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:34:14

US3952104

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

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:34:14

US3952104

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

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

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)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:34:14

US3952104

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

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered 'mRNA-1273'	System	24 Mar 2021 13:34:14
DataPoint set to visible.	System	12 Mar 2021 14:36:12

US3952104

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

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:34:14

US3952104

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

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '13:33'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:34:14

US3952104

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

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered '04 Mar 2021 13:33'	System	24 Mar 2021 13:34:14

US3952104

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

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:34:14

US3952104

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

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered 'ONCE'	System	24 Mar 2021 13:34:14

US3952104

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

Form: Exposure

Generated On: 10 Jun 2021 10:29:57

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered 'INTRAMUSCULAR'	System	24 Mar 2021 13:34:14

US3952104

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:36:37

US3952104

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 14:36:56
User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	12 Mar 2021 14:36:37
User entered '02 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 14:36:37

US3952104

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '16:24'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:36:37

US3952104

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered '02 Mar 2021 16:24'	System	12 Mar 2021 14:36:37

US3952104

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:29:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:33:55

US3952104

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:29:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-Query: Response noted that two nasal swabs were collected. However, per Preclarus report there is only one Swab Sample dated 02-Mar-2021 with Accession No: 1F602597915 and Requisition Kit ID : 1F600475679. Swab dated 04-Mar-2020 is missing in PPD Central labs. Kindly review Preclarus and make updates as appropriate in Preclarus and EDC. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	29 Apr 2021 10:27:17
	Mimi Van Der Leden	09 Apr 2021 20:15:56
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-Query: Response noted that two nasal swabs were collected. However, per Preclarus report there is only one Swab Sample dated 02-Mar-2021 with Accession No: 1F602597915 and Requisition Kit ID : 1F600475679. Swab dated 04-Mar-2020 is missing in PPD Central labs. Kindly review Preclarus and make updates as appropriate in Preclarus and EDC. Thank you.' answered with 'Requisition Kit ID 1F17783447' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 15:01:47
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-Query: Response noted that two nasal swabs were collected. However, per Preclarus report there is only one Swab Sample dated 02-Mar-2021 with Accession No: 1F602597915 and Requisition Kit ID : 1F600475679. Swab dated 04-Mar-2020 is missing in PPD Central labs. Kindly review Preclarus and make updates as appropriate in Preclarus and EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 09:56:43
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 04-MAR-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 02-MAR-2021 in PPD Central lab. Please review and confirm the correct date and update in EDC and PPD Portal as appropriate. Else clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 09:56:43

US3952104

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:29:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 04-MAR-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 02-MAR-2021 in PPD Central lab. Please review and confirm the correct date and update in EDC and PPD Portal as appropriate. Else clarify, Thank you.' answered with 'Nasal Swab was collected on both dates. Sample collected on 02Mar2021 was for Participant Decision Visit, and 04Mar2021 was for OL-1 Visit.' (Site from DM).	Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:04:23
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 04-MAR-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 02-MAR-2021 in PPD Central lab. Please review and confirm the correct date and update in EDC and PPD Portal as appropriate. Else clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:59:19
User entered '04 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 13:33:55

US3952104

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:29:57

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:15:56
User entered '12:30'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 13:33:55

US3952104

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:29:57

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered '04 Mar 2021 12:30'	System	24 Mar 2021 13:33:55

US3952104

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

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 14:39:38

US3952104

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

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:05
User entered '1'	System	12 Mar 2021 14:39:38

US3952104

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4)	05 Apr 2021 19:10:32
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '12 Mar 2021'	Nick Bart (b) (4)	05 Apr 2021 19:10:32

US3952104

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:10:32

US3952104

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:29:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	05 Apr 2021 19:10:32
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	05 Apr 2021 19:10:36

US3952104

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:52
User entered '1'	System	05 Apr 2021 19:10:36

US3952104

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:29:57

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:52
User entered '1'	System	05 Apr 2021 19:10:36
DataPoint set to visible.	System	05 Apr 2021 19:10:36

US3952104

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	05 Apr 2021 19:13:15
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered '01 Apr 2021'	Nick Bart (b) (4)	05 Apr 2021 19:13:15
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'Clinic (Clinic)'	Nick Bart (b) (4)	05 Apr 2021 19:13:15
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:29:57

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	05 Apr 2021 19:13:15

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	05 Apr 2021 19:13:20
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Apr 2021 19:13:20
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Apr 2021 19:13:20
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:13:20

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Apr 2021 19:13:20
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Apr 2021 19:13:20
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Apr 2021 19:13:20
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Apr 2021 19:13:20
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:13:20

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Apr 2021 19:13:20
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:13:20

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Apr 2021 19:13:20
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:13:20

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Apr 2021 19:13:20
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:29:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:13:20

US3952104

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	05 Apr 2021 19:13:28
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:29:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	05 Apr 2021 19:13:28
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	05 Apr 2021 19:13:42
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered '01 Apr 2021'	Nick Bart (b) (4)	05 Apr 2021 19:13:42
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered '10:30'	Nick Bart (b) (4)	05 Apr 2021 19:13:42
	(b) (4)	

US3952104

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:29:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 10:30'	System	05 Apr 2021 19:13:42

US3952104

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:29:57

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:55
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:10:31
DataPoint Verified.	(b) (4)	30 Oct 2020 20:39:22
User entered 'Yes (Y)'	Mimi Van Der Leden	19 Oct 2020 16:29:28

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 20:59:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:10
User entered	System	20 Oct 2020 14:21:06
'USA-US215-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	20 Oct 2020 14:21:06

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Hip fracture - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 16:39:28
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 16:39:28
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 16:38:35
User entered 'Hip fracture'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered 'Yes (Y)'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered 'No (N)'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered 'No (N)'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered '05 Oct 2020'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered empty.	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:37:56

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered 'No (N)'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered '08 Oct 2020'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered empty.	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:37:56

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered 'Yes (Y)'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered '0'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered '0'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered '1'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:22:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:50:46
User closed query 'PV Query: Please confirm if the hospitalization date was 07 Oct 2020 or 08 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:12:01
Query 'PV Query: Please confirm if the hospitalization date was 07 Oct 2020 or 08 Oct 2020.' answered with 'updated' (Site from Safety).	Nick Bart (b) (4)	10 Nov 2020 22:04:32
DataPoint Un-verified.	Nick Bart (b) (4)	10 Nov 2020 22:04:28
Signature has been broken.	(b) (4) Nick Bart (b) (4)	10 Nov 2020 22:04:28
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4) Nick Bart (b) (4)	10 Nov 2020 22:04:28
User opened query 'PV Query: Please confirm if the hospitalization date was 07 Oct 2020 or 08 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:38:09
User closed query 'PV Query: It was reported that the subject remained hospitalized after event resolved. Please provide the reason for the subject's prolonged hospitalization. Please consider reconciling event/hospitalization dates or report additional events as necessary.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 21:29:18
Query 'PV Query: It was reported that the subject remained hospitalized after event resolved. Please provide the reason for the subject's prolonged hospitalization. Please consider reconciling event/hospitalization dates or report additional events as necessary.' answered with 'left hip fracture repaired on 08OCT2020 and discharged to SNF ON 12OCT2020 for PT' (Site from Safety).	Mimi Van Der Leden (b) (4)	30 Oct 2020 20:55:36
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: It was reported that the subject remained hospitalized after event resolved. Please provide the reason for the subject's prolonged hospitalization. Please consider reconciling event/hospitalization dates or report additional events as necessary.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	27 Oct 2020 14:13:55
User entered '08 Oct 2020'	Mimi Van Der Leden (b) (4)	19 Oct 2020 16:59:56
	Mimi Van Der Leden (b) (4)	19 Oct 2020 16:37:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User closed query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' (Site from System).	System	19 Oct 2020 16:39:50
Query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' answered by data change (Site from System).	System	19 Oct 2020 16:39:50
User entered '12 Oct 2020' reason for change: Data Entry Error	Mimi Van Der Leden	19 Oct 2020 16:39:50
	(b) (4)	
User opened query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' (Site from System).	System	19 Oct 2020 16:37:56
User entered '12 Sep 2020'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:50:48
User closed query 'PER CDM: RE-QUERY: Per previous query response it was reported that "medical records pending". However, please consider checking YES/NO for Admitted to ICU? If appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:59:04
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 20:59:30
Query 'PER CDM: RE-QUERY: Per previous query response it was reported that "medical records pending". However, please consider checking YES/NO for Admitted to ICU? If appropriate. Thank you.' answered with 'updated' (Site from DM).	Mimi Van Der Leden	30 Oct 2020 20:56:07
Signature has been broken.	Mimi Van Der Leden	30 Oct 2020 20:55:55
User entered 'No (N)' reason for change: Data Entry Error	Mimi Van Der Leden	30 Oct 2020 20:55:55
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:31
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User opened query 'PER CDM: RE-QUERY: Per previous query response it was reported that "medical records pending". However, please consider checking YES/NO for Admitted to ICU? If appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:44:47
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 16:44:30
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'medical records pending' (Site from System).	Mimi Van Der Leden	19 Oct 2020 16:38:51

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Oct 2020 16:37:56
User entered 'Unknown (UNK)'	Mimi Van Der Leden (b) (4)	19 Oct 2020 16:37:56

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 21:09:37
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:33
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
User entered empty.	(b) (4) Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 21:09:35
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:35
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
User entered '0'	(b) (4) Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 21:09:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:40
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
User entered '0'	(b) (4) Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 21:09:32
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:44
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
User entered '0'	Mimi Van Der Leden	19 Oct 2020 16:37:56

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

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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)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However, Exposure form(V2D29) and Dosing Discontinuation form (End of study folder) is not updated. Please review and update accordingly or provide clarification. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 11:40:52
	(b) (4), (b) (6)	03 Dec 2020 21:13:37
Query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However, Exposure form(V2D29) and Dosing Discontinuation form (End of study folder) is not updated. Please review and update accordingly or provide clarification. Thank you.' answered with 'All pages updated' (Site from DM).	Nick Bart (b) (4)	02 Dec 2020 17:51:48
User opened query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However, Exposure form(V2D29) and Dosing Discontinuation form (End of study folder) is not updated. Please review and update accordingly or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:09:13
User closed query 'Per source SAE 1 form, this is discrepant. Please update if necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 02:30:10
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 20:59:30
Query 'Per source SAE 1 form, this is discrepant. Please update if necessary.' answered with 'updated' (Site from CRA).	(b) (4)	30 Oct 2020 20:56:48
Signature has been broken.	Mimi Van Der Leden	30 Oct 2020 20:56:39
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4)	30 Oct 2020 20:56:39
User opened query 'Per source SAE 1 form, this is discrepant. Please update if necessary.' (Site from CRA).	Mimi Van Der Leden	30 Oct 2020 20:43:22
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 20:42:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered 'Dose Delayed (DOSE DELAYED)'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

None

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:22:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:13:47
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:28:09
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	05 Nov 2020 19:35:37
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Nick Bart (b) (4)	05 Nov 2020 19:35:25
User entered '0' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	Nick Bart (b) (4)	05 Nov 2020 19:35:25
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 06:47:10
User signature succeeded.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	Mimi Van Der Leden	19 Oct 2020 16:59:56
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '0'	System	19 Oct 2020 16:39:50
	Mimi Van Der Leden	19 Oct 2020 16:39:50
	(b) (4)	
	System	19 Oct 2020 16:37:56
	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:22:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:13:50
DataPoint Un-verified.	Nick Bart (b) (4)	05 Nov 2020 19:35:25
Signature has been broken.	(b) (4) Nick Bart (b) (4)	05 Nov 2020 19:35:25
User entered '1' reason for change: Data Entry Error	(b) (4) Nick Bart (b) (4)	05 Nov 2020 19:35:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
User entered '0'	(b) (4) Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

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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 21:22:14
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 13:39:24
Signature has been broken.	(b) (4), (b) (6)	24 Mar 2021 13:39:24
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
User entered '0'	(b) (4)	
	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(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)	30 Oct 2020 20:40:22
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
	(b) (4)	
User entered empty.	Mimi Van Der Leden	19 Oct 2020 16:37:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = PT AND OT BEGAN IN HOSPITAL WAS DISCHARGED TO A SNF ON 12OCT2020 FOR CONTINUED PT. 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)	14 Feb 2021 10:24:40
User closed query 'Per DM CLR: SAE Narrative = SUBJECT FELL ON 05OCT2020. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 10:24:38
Query 'Per DM CLR: SAE Narrative = PT AND OT BEGAN IN HOSPITAL WAS DISCHARGED TO A SNF ON 12OCT2020 FOR CONTINUED PT. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	09 Feb 2021 19:37:14
Query 'Per DM CLR: SAE Narrative = SUBJECT FELL ON 05OCT2020. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Fall does not need reported as AE' (Site from DM).	Nick Bart (b) (4)	09 Feb 2021 19:36:01
User opened query 'Per DM CLR: SAE Narrative = PT AND OT BEGAN IN HOSPITAL WAS DISCHARGED TO A SNF ON 12OCT2020 FOR CONTINUED PT. 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 Dec 2020 05:35:28
User opened query 'Per DM CLR: SAE Narrative = SUBJECT FELL ON 05OCT2020. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 05:35:18
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 21:25:54

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per SAE narrative, Subject was "ADMITTED TO HOSPITAL WITH A LEFT FEMORAL NECK FRACTURE. HAD SURGERY 08OCT2020; PROCEDURE WAS A LEFT TROCHANTERIC NAILING", however no surgery is recorded in Concomitant procedures eCRF. Please kindly update the performed surgery in the Concomitant procedures form. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:41:08
Query 'Per CDM: Per SAE narrative, Subject was "ADMITTED TO HOSPITAL WITH A LEFT FEMORAL NECK FRACTURE. HAD SURGERY 08OCT2020; PROCEDURE WAS A LEFT TROCHANTERIC NAILING", however no surgery is recorded in Concomitant procedures eCRF. Please kindly update the performed surgery in the Concomitant procedures form. Thank you.' answered with 'Procedure added to appropriate folder' (Site from DM).	Nick Bart (b) (4) (b) (4)	02 Dec 2020 17:53:16
User opened query 'Per CDM: Per SAE narrative, Subject was "ADMITTED TO HOSPITAL WITH A LEFT FEMORAL NECK FRACTURE. HAD SURGERY 08OCT2020; PROCEDURE WAS A LEFT TROCHANTERIC NAILING", however no surgery is recorded in Concomitant procedures eCRF. Please kindly update the performed surgery in the Concomitant procedures form. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:17:07
User closed query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 21:30:31
User closed query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 21:30:26
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 21:30:21

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 21:30:12
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 21:30:06
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)	02 Nov 2020 21:29:29
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 20:59:30
Query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' answered with 'no/updated' (Site from Safety).	(b) (4) Mimi Van Der Leden	30 Oct 2020 20:58:27
Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' answered with 'accidental - muscle cramp' (Site from Safety).	(b) (4)	
Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' answered with 'accidental - muscle cramp' (Site from Safety).	Mimi Van Der Leden	30 Oct 2020 20:58:14
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'narrative updated' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'narrative updated' (Site from Safety).	Mimi Van Der Leden	30 Oct 2020 20:57:53
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'narrative updated' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'narrative updated' (Site from Safety).	Mimi Van Der Leden	30 Oct 2020 20:57:45
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'narrative updated' (Site from Safety).	(b) (4)	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'not applicable' (Site from Safety).	Mimi Van Der Leden (b) (4)	30 Oct 2020 20:57:29
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 negative on 07OCT2020' (Site from Safety).	Mimi Van Der Leden (b) (4)	30 Oct 2020 20:57:16
DataPoint Un-verified.	Mimi Van Der Leden (b) (4)	30 Oct 2020 20:53:47
Signature has been broken.	Mimi Van Der Leden (b) (4)	30 Oct 2020 20:53:47
User entered 'SUBJECT FELL AND FRACTURED HIP. ADMITTED TO HOSPITAL; DISCHARGED TO REHAB. FURTHER DETAILS UPON RECEIPT OF MEDICAL RECORDS.	Mimi Van Der Leden (b) (4)	30 Oct 2020 20:53:47
Upon receipt of medical record, further information is available. Subject fell on 05OCT2020 and lay on floor until taken to hospital on 07OCT2020. Admitted to hospital with a Left femoral neck fracture. Had surgery 08OCT2020; procedure was a left trochanteric nailing. Pt had an uncomplicated course. PT and OT began in hospital. Was discharged to a SNF on 12OCT2020 for continued PT. Discharged home on 24OCT2020. Of note, tested covid negative in hospital.' reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:40:22
User opened query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:15:05
User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:14:58

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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 provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:14:33
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:14:26
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:14:16
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)	27 Oct 2020 14:14:08
User signature succeeded.	Mimi Van Der Leden	19 Oct 2020 16:59:56
User entered 'Subject fell and fractured hip. Admitted to hospital; discharged to rehab. Further details upon receipt of medical records.'	(b) (4) Mimi Van Der Leden	19 Oct 2020 16:37:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:37:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:37:56

US3952104

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:29:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Oct 2020 16:37:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:29:57

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:55
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:52:46

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Dec 2020 17:47:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 17:47:54
Data point term sent to Coder Coding entries removed.	System Nick Bart (b) (4) (b) (4)	02 Dec 2020 17:46:54 02 Dec 2020 17:46:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 13:54:41
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 Sep 2020 13:54:41
Data point term sent to Coder User entered 'benadryl'	System Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:54:01 21 Sep 2020 13:53:38

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of Allergies. Reconcile with MH entry so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 11:17:40
Query 'Per DM CLR: Please update the indication to reflect the location and type of Allergies. Reconcile with MH entry so there is an appropriate match. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	02 Dec 2020 17:46:31
User entered 'seasonal ALLERGIES' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	02 Dec 2020 17:46:27
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of Allergies. Reconcile with MH entry so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:23:54
User entered 'allergies'	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:53:38

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered '25'	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'as needed (PRN)'	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'un UNK 2020'	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	21 Sep 2020 13:53:38
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 13:53:38

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 13:53:38

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 13:53:38

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, PRODUCT: BORON;CHROMIUM;COPPER;GERMANIUM;IODINE;MANGANESE;MOLYBDENUM;SELENIUM;SILICON;SITOSTEROL;VANADIUM;VITAMIN D NOS;ZINC, PRODUCTSYNONYM: SUPER BETA PROSTATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Sep 2020 13:56:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 13:56:39
Data point term sent to Coder	System	21 Sep 2020 13:56:02
User entered 'super beta prostate'	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:55:27

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'enlarged prostate'	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered '250'	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'twice daily (BID)'	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'un UNK 2014'	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	21 Sep 2020 13:55:27
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Sep 2020 13:55:27

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 13:55:27

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 13:55:27

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Sep 2020 13:57:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 13:57:43
Data point term sent to Coder	System	21 Sep 2020 13:57:03
User entered 'pneumovax'	Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'pneumonia vaccine'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0.5'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'mL (mL)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	21 Sep 2020 13:56:12
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'once (ONCE)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	21 Sep 2020 13:56:12
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'un Apr 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'un Apr 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	21 Sep 2020 13:56:12
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User entered empty.	System	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User entered empty.	System	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:42:08
User entered empty.	System	21 Sep 2020 13:56:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 05:32:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:32:17
Data point term sent to Coder	System	03 Nov 2020 19:50:46
User entered 'tylenol [acetaminophen]'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	03 Nov 2020 19:50:01
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'hip fracture'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
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 or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:53:49
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'confirmed data is correct as entered' (Site from DM).	Nick Bart (b) (4) (b) (4)	28 Jan 2021 17:14:37
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 or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 02:28:27
User entered '400'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Nick Bart (b) (4)	28 Jan 2021 17:14:29
User entered 'mL (mL)'	(b) (4)	
	Nick Bart (b) (4)	03 Nov 2020 19:50:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'ml/hour' reason for change: Data Entry Error	(b) (4)	28 Jan 2021 17:14:29
User entered empty.	Nick Bart (b) (4)	03 Nov 2020 19:50:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'twice daily (BID)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '08 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '08 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User entered '2'	System	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User entered '1'	System	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:52
User entered '804 (804)'	System	03 Nov 2020 19:50:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 05:32:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:32:16
Data point term sent to Coder	System	03 Nov 2020 19:51:49
User entered 'tylenol [acetaminophen]'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'hip fracture'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '650'	(b) (4)	03 Nov 2020 19:51:25
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'other (OTHER)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'every 6 hours'	(b) (4)	03 Nov 2020 19:51:25
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	03 Nov 2020 19:51:25
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 10:00:41
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'Subject was taking this medication in conjunction with physical therapy, and so indication is still for treatment of AE' (Site from DM).	Nick Bart (b) (4) (b) (4)	28 Jan 2021 17:21:13
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 02:29:35
User entered '09 Oct 2020'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '11 Oct 2020'	(b) (4)	03 Nov 2020 19:51:25
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	03 Nov 2020 19:51:25
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User entered empty.	System	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User entered empty.	System	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:38:56
User entered empty.	System	03 Nov 2020 19:51:25

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CITRATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 04:55:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 04:55:18
Data point term sent to Coder	System	03 Nov 2020 19:52:50
User entered 'calcium citrate'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	03 Nov 2020 19:52:08
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'hip fracture'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
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 or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:59:25
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	28 Jan 2021 17:24:02
User entered '950' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	28 Jan 2021 17:23:46
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 or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 02:29:46
User entered '980'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '09 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '12 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User entered '1'	System	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User entered '1'	System	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:03
User entered '804 (804)'	System	03 Nov 2020 19:52:08

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
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 - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 04:56:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 04:56:19
Data point term sent to Coder	System	03 Nov 2020 19:58:58
User entered 'cefazolin'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'hip fracture'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '2'	Nick Bart	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'g (g)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'other (OTHER)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'every 8 hours'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Nick Bart (b) (4)	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '08 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	Nick Bart	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '08 Oct 2020'	(b) (4)	
	Nick Bart (b) (4)	03 Nov 2020 19:57:56
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User entered empty.	System	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User entered empty.	System	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:09
User entered empty.	System	03 Nov 2020 19:57:56

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	03 Nov 2020 20:04:28
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	03 Nov 2020 20:04:28
Data point term sent to Coders	System	03 Nov 2020 20:03:05
User entered 'vitamin d3'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'hip fracture'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '2000'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'IU (IU)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	03 Nov 2020 20:02:44
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '09 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '12 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	03 Nov 2020 20:02:44
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User entered '1'	System	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User entered '1'	System	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:12
User entered '804 (804)'	System	03 Nov 2020 20:02:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 05:02:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:02:23
Data point term sent to Coder	System	03 Nov 2020 20:04:07
User entered 'enoxaprin [lovenox]'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	03 Nov 2020 20:03:33
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'hip fracture'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '40'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	03 Nov 2020 20:03:33
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '07 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	Nick Bart	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	03 Nov 2020 20:03:33
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '12 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	03 Nov 2020 20:03:33
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User entered '1'	System	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User entered '1'	System	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:19
User entered '804 (804)'	System	03 Nov 2020 20:03:33

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
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.	(b) (4) Coder Import (b) (4) (b) (4)	03 Nov 2020 20:07:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 20:07:30
Data point term sent to Coder	System	03 Nov 2020 20:06:13
User entered 'lactated ringers'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	03 Nov 2020 20:05:22
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'hip fracture'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '100'	(b) (4)	03 Nov 2020 20:05:22
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Other (OTHER)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'cc per hour'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'other (OTHER)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'continuous'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	03 Nov 2020 20:05:22
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '07 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	Nick Bart (b) (4)	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '08 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User entered empty.	System	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User entered empty.	System	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:29
User entered empty.	System	03 Nov 2020 20:05:22

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 05:20:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:20:20
Data point term sent to Coder	System	03 Nov 2020 20:07:14
User entered 'morphine'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'hip fracture'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '1'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	03 Nov 2020 20:06:44
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'other (OTHER)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'every four hours prn'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '08 Oct 2020'	(b) (4)	
	Nick Bart (b) (4)	03 Nov 2020 20:06:44
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '08 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	03 Nov 2020 20:06:44
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User entered empty.	System	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User entered empty.	System	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:48
User entered empty.	System	03 Nov 2020 20:06:44

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 00:15:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:15:27
Data point term sent to Coder	System	03 Nov 2020 20:08:16
User entered 'zofran'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'nausea prevention'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '4'	Nick Bart (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'other (OTHER)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'every six hours prn'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	03 Nov 2020 20:07:58
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '08 Oct 2020'	(b) (4)	
	Nick Bart (b) (4)	03 Nov 2020 20:07:58
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '08 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User entered empty.	System	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User entered empty.	System	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:53
User entered empty.	System	03 Nov 2020 20:07:58

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	03 Nov 2020 20:10:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 20:10:25
Data point term sent to Coder	System	03 Nov 2020 20:09:16
User entered 'miralax'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'constipation prevention'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '1'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Other (OTHER)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'packet'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	03 Nov 2020 20:08:51
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '11 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '12 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User entered '1'	System	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User entered '1'	System	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:56
User entered '804 (804)'	System	03 Nov 2020 20:08:51

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
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: SENOKOT - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	03 Nov 2020 20:15:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 20:15:48
Data point term sent to Coder	System	03 Nov 2020 20:15:45
User entered 'senokot'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'constipation prevention'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '8.6/50'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'other (OTHER)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'qhs'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '07 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '11 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User entered empty.	System	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User entered empty.	System	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:01
User entered empty.	System	03 Nov 2020 20:15:09

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:29:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:29:42
User signature succeeded.	Mimi Van Der Leden (b) (4)	08 Apr 2021 19:51:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:29:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:29:17
Data point term sent to Coder	System	03 Nov 2020 20:17:48
User entered 'sodium chloride 0.9%'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'hip fracture'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '125'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Other (OTHER)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'cc per hour'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'other (OTHER)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'continuous'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '07 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	Nick Bart (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '07 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User entered empty.	System	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User entered empty.	System	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:07
User entered empty.	System	03 Nov 2020 20:17:05

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Nov 2020 20:21:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 20:21:29
Data point term sent to Coder	System	03 Nov 2020 20:20:52
User entered 'eliquis'	Nick Bart (b) (4) (b) (4)	03 Nov 2020 20:20:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'deep vein thrombosis prophylaxis'	(b) (4)	
	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered '2.5'	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'twice daily (BID)'	(b) (4)	
	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '10 Oct 2020'	(b) (4)	
	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4)	
	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	
	Nick Bart (b) (4)	03 Nov 2020 20:20:01
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Nov 2020 20:20:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:20:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 20:20:01

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Feb 2021 19:44:34
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 Feb 2021 19:44:34
Data point term sent to Coder Coding entries removed.	System Nick Bart (b) (4) (b) (4)	09 Feb 2021 19:43:37 09 Feb 2021 19:43:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 13:25:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 13:25:12
Data point term sent to Coder User entered 'vitamin d3'	System Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:40 24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 10:04:42
' (Site from DM).		
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	24 Mar 2021 13:32:17
' answered with 'updated' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 13:32:10
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	10 Mar 2021 10:16:03
' (Site from DM).		
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Per CDM: Indication was recorded as 'PROPHYLAXIS/BONE HEALTH [SECONDARY TO HIP FRACTURE]'. However, Prophylaxis is recorded as NO. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 10:04:50
Query 'Per CDM: Indication was recorded as 'PROPHYLAXIS/BONE HEALTH [SECONDARY TO HIP FRACTURE]'. However, Prophylaxis is recorded as NO. Please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 13:32:22
User opened query 'Per CDM: Indication was recorded as 'PROPHYLAXIS/BONE HEALTH [SECONDARY TO HIP FRACTURE]'. However, Prophylaxis is recorded as NO. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 10:05:29
User entered 'prophylaxis/bone health [secondary to HIP FRACTURE]' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	09 Feb 2021 19:43:18
User entered 'hip fracture'	Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '2000'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'IU (IU)'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Feb 2021 10:25:15
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'Indication updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	09 Feb 2021 19:43:26
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 05:55:01
User entered '01 Nov 2020'	Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Feb 2021 19:38:07
User entered 'Yes (Y)'	Nick Bart (b) (4)	24 Nov 2020 13:24:17
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '21 Nov 2020' reason for change: Data Entry Error	(b) (4)	09 Feb 2021 19:38:07
User entered empty.	Nick Bart (b) (4)	24 Nov 2020 13:24:17
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4) Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User entered '1'	System	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User entered '1'	System	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:40:23
User entered '804 (804)'	System	24 Nov 2020 13:24:17

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CITRATE, PRODUCTSYNONYM: CALCITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 19:45:36
	(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 Feb 2021 19:45:36
	(b) (4)	
Data point term sent to Coder	System	09 Feb 2021 19:44:39
Coding entries removed.	Nick Bart (b) (4)	09 Feb 2021 19:43:43
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CITRATE, PRODUCTSYNONYM: CALCITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 13:26:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 13:26:53
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 13:25:41
User entered 'calcitrate'	Nick Bart (b) (4)	24 Nov 2020 13:25:12
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 10:05:09
' (Site from DM).		
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	24 Mar 2021 13:40:55
' answered with 'updated' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 13:40:49
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	10 Mar 2021 10:16:14
' (Site from DM).		
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:25:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Per CDM: Indication was recorded as 'PROPHYLAXIS/BONE HEALTH [SECONDARY TO HIP FRACTURE]'. However, Prophylaxis is recorded as NO. Please review and update as appropriate. Thank you.' (Site from DM). Query 'Per CDM: Indication was recorded as 'PROPHYLAXIS/BONE HEALTH [SECONDARY TO HIP FRACTURE]'. However, Prophylaxis is recorded as NO. Please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 10:05:06
User opened query 'Per CDM: Indication was recorded as 'PROPHYLAXIS/BONE HEALTH [SECONDARY TO HIP FRACTURE]'. However, Prophylaxis is recorded as NO. Please review and update as appropriate. Thank you.' (Site from DM). User entered 'PROPHYLAXIS/BONE HEALTH [SECONDARY TO HIP FRACTURE]' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 13:41:01
User entered 'hip fracture'	(b) (4), (b) (6)	17 Feb 2021 10:06:04
	Nick Bart (b) (4) (b) (4)	09 Feb 2021 19:43:43
	Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:25:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered '950'	Nick Bart (b) (4)	24 Nov 2020 13:25:12
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	24 Nov 2020 13:25:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Nov 2020 13:25:12
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'once daily (QD)'	(b) (4)	
	Nick Bart (b) (4)	24 Nov 2020 13:25:12
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Nov 2020 13:25:12
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	24 Nov 2020 13:25:12
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Nov 2020 13:25:12
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Feb 2021 10:25:34
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'Indication updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	09 Feb 2021 19:43:50
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 05:55:09
User entered '01 Nov 2020'	Nick Bart (b) (4) (b) (4)	24 Nov 2020 13:25:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '0'	(b) (4)	
	Nick Bart (b) (4)	24 Nov 2020 13:25:12
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	24 Nov 2020 13:25:12
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Nov 2020 13:25:12
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'No (N)'	(b) (4)	
	Nick Bart (b) (4)	24 Nov 2020 13:25:12
	(b) (4)	

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 13:25:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 13:25:12

US3952104

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:29:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 13:25:12

US3952104

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:29:57

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:55
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Yes (Y)'	(b) (4)	02 Dec 2020 17:52:25
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:29:57

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered '08 Oct 2020'	Nick Bart (b) (4)	02 Dec 2020 17:52:52
	(b) (4)	

US3952104

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:29:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered 'LEFT TROCHANTERIC NAILING'	Nick Bart (b) (4)	02 Dec 2020 17:52:52
	(b) (4)	

US3952104

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
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)	25 Mar 2021 08:25:40
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).	(b) (4), (b) (6)	24 Mar 2021 13:40:01
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)	11 Mar 2021 08:26:44
User entered 'Adverse Event (AE)'	Nick Bart (b) (4) (b) (4)	02 Dec 2020 17:52:52

US3952104

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:29:57

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 17:52:52
	(b) (4)	

US3952104

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:29:57

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:08:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Per DM CLR: Please review the Date of this procedure, as it is out of the expected timeframe of AE #1 HIP FRACTURE (05 OCT 2020-08 OCT 2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 12:25:47
Query 'Per DM CLR: Please review the Date of this procedure, as it is out of the expected timeframe of AE #1 HIP FRACTURE (05 OCT 2020-08 OCT 2020). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'Data is correct as entered per patient and records. Subject continued physical therapy beyond dates of hip fracture as ongoing treatment.' (Site from DM).	Nick Bart (b) (4) (b) (4)	09 Mar 2021 14:25:03
User opened query 'Per DM CLR: Please review the Date of this procedure, as it is out of the expected timeframe of AE #1 HIP FRACTURE (05 OCT 2020-08 OCT 2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 14:11:08
User entered '12 Oct 2020'	Nick Bart (b) (4) (b) (4)	09 Feb 2021 19:36:47

US3952104

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:29:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:08:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Continued physical therapy for fractured left hip'	(b) (4) Nick Bart (b) (4) (b) (4)	09 Feb 2021 19:36:47

US3952104

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:29:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:08:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered 'Adverse Event (AE)'	(b) (4)	09 Feb 2021 19:36:47
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:29:57

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:08:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered empty.	(b) (4)	09 Feb 2021 19:36:47
	Nick Bart (b) (4)	
	(b) (4)	

US3952104

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:29:57

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:52:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
User entered '19 Oct 2020' reason for change: Data Entry Error	Atanas Filev (b) (4)	13 Jan 2021 22:34:46
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 21:10:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 21:10:10
User entered '05 Oct 2020'	Nick Bart (b) (4)	02 Dec 2020 17:51:20
	(b) (4)	

US3952104

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:29:57

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:52:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 21:10:28
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 21:10:10
User entered 'AE (specify) (ADVERSE EVENT)'	Nick Bart (b) (4)	02 Dec 2020 17:51:20
	(b) (4)	

US3952104

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:29:57

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:52:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User closed query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1).' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 10:05:19
Query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1).' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 13:37:29
User entered '#1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 13:37:23
User opened query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1).' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:50:33
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:49:48
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:28:54
User closed query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 12:57:26

PRODUCTION RELEASE (v12.003
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US3952104

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:29:57

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	22 Dec 2020 15:57:08
User entered '1' reason for change: Data Entry Error	Nick Bart (b) (4)	22 Dec 2020 15:57:04
User entered 'AE #1' reason for change: Data Entry Error	Nick Bart (b) (4)	22 Dec 2020 15:56:52
User opened query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:31:03
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 21:10:29
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 21:10:10
User entered 'Left Fracture Hip'	Nick Bart (b) (4)	02 Dec 2020 17:51:20

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'USA-US215-2020-MRNA-1273-P301000003'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Mimi'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Van Der Leden'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '15201 Shady Grove Dr'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Rockville'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 22:33:35
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
User entered empty.	(b) (4)	30 Oct 2020 21:01:14

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '20850'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	30 Oct 2020 20:37:51
	(b) (4), (b) (6)	
User entered 'US'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	25 Mar 2021 14:03:43
User entered '4'	System	11 Nov 2020 20:33:13
User entered '3'	System	06 Nov 2020 18:33:44
Signature has been broken.	System	02 Nov 2020 21:31:20
User entered '2'	System	02 Nov 2020 21:31:20
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
	(b) (4)	
User entered '1'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered	System	20 Oct 2020 14:21:06
'USA-US215-2020-MRNA-1273-P301000003'		

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Mimi'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Van Der Leden'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '15201 Shady Grove Dr'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Rockville'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 22:33:35
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
User entered empty.	(b) (4)	30 Oct 2020 21:01:14

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '20850'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	30 Oct 2020 20:37:51
	(b) (4), (b) (6)	
User entered 'US'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	25 Mar 2021 14:03:43
User entered '4'	System	11 Nov 2020 20:33:13
User entered '3'	System	06 Nov 2020 18:33:44
Signature has been broken.	System	02 Nov 2020 21:31:20
User entered '2'	System	02 Nov 2020 21:31:20
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
	(b) (4)	
User entered '1'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:29:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:47:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 21:34:53
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:37:51
User entered '20/Oct/2020 14:21'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:29:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:47:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 21:34:53
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:37:51
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'USA-US215-2020-MRNA-1273-P301000003'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Mimi'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Van Der Leden'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '15201 Shady Grove Dr'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Rockville'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 22:33:35
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
User entered empty.	(b) (4)	30 Oct 2020 21:01:14

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '20850'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	30 Oct 2020 20:37:51
	(b) (4), (b) (6)	
User entered 'US'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	25 Mar 2021 14:03:43
User entered '4'	System	11 Nov 2020 20:33:13
User entered '3'	System	06 Nov 2020 18:33:44
Signature has been broken.	System	02 Nov 2020 21:31:20
User entered '2'	System	02 Nov 2020 21:31:20
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
	(b) (4)	
User entered '1'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:29:57

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:29:53
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 22:17:16
	(b) (4)	
User entered '30/Oct/2020 18:16' reason for change:	Mimi Van Der Leden	30 Oct 2020 22:16:46
Data Entry Error	(b) (4)	
Signature has been broken.	Mimi Van Der Leden	30 Oct 2020 22:15:33
	(b) (4)	
User entered '30/Oct/2020 18:15' reason for change:	Mimi Van Der Leden	30 Oct 2020 22:15:33
Data Entry Error	(b) (4)	
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
	(b) (4)	
User entered '30/Oct/2020 17:00'	Mimi Van Der Leden	30 Oct 2020 21:01:14
	(b) (4)	

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:29:57

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	08 Apr 2021 19:51:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:29:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:29
User entered '0'	(b) (4), (b) (6)	02 Nov 2020 21:31:20
User closed query 'Please complete.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 22:33:18
Query 'Please complete.' answered with 'updated' (Site from CRA).	Mimi Van Der Leden (b) (4)	30 Oct 2020 21:52:26
User opened query 'Please complete.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 21:35:12

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'USA-US215-2020-MRNA-1273-P301000003'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Mimi'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Van Der Leden'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '15201 Shady Grove Dr'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Rockville'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 22:33:35
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
User entered empty.	(b) (4)	30 Oct 2020 21:01:14

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '20850'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	30 Oct 2020 20:37:51
	(b) (4), (b) (6)	
User entered 'US'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	25 Mar 2021 14:03:43
User entered '4'	System	11 Nov 2020 20:33:13
User entered '3'	System	06 Nov 2020 18:33:44
Signature has been broken.	System	02 Nov 2020 21:31:20
User entered '2'	System	02 Nov 2020 21:31:20
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
	(b) (4)	
User entered '1'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:29:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 20:47:47
User entered '02/Nov/2020 21:31'	System	02 Nov 2020 21:31:20

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:29:57

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	08 Apr 2021 19:51:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:47:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:29
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 21:31:20

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'USA-US215-2020-MRNA-1273-P301000003'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Mimi'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Van Der Leden'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '15201 Shady Grove Dr'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Rockville'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 22:33:35
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
User entered empty.	(b) (4)	30 Oct 2020 21:01:14

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '20850'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	30 Oct 2020 20:37:51
	(b) (4), (b) (6)	
User entered 'US'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	25 Mar 2021 14:03:43
User entered '4'	System	11 Nov 2020 20:33:13
User entered '3'	System	06 Nov 2020 18:33:44
Signature has been broken.	System	02 Nov 2020 21:31:20
User entered '2'	System	02 Nov 2020 21:31:20
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
	(b) (4)	
User entered '1'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:29:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 20:47:56
User entered '06/Nov/2020 18:33'	System	06 Nov 2020 18:33:44

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:29:57

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	08 Apr 2021 19:51:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:03:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:47:58
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 18:33:44

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'USA-US215-2020-MRNA-1273-P301000003'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Mimi'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Van Der Leden'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '15201 Shady Grove Dr'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Rockville'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 22:33:35
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
User entered empty.	(b) (4)	30 Oct 2020 21:01:14

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '20850'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	30 Oct 2020 20:37:51
	(b) (4), (b) (6)	
User entered 'US'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	25 Mar 2021 14:03:43
User entered '4'	System	11 Nov 2020 20:33:13
User entered '3'	System	06 Nov 2020 18:33:44
Signature has been broken.	System	02 Nov 2020 21:31:20
User entered '2'	System	02 Nov 2020 21:31:20
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
	(b) (4)	
User entered '1'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:29:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 20:48:03
User entered '11/Nov/2020 15:33'	System	11 Nov 2020 20:33:13

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:29:57

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	08 Apr 2021 19:51:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:03:27
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:48:05
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 20:33:13

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'USA-US215-2020-MRNA-1273-P301000003'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Yes (Y)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'No (N)'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Mimi'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Van Der Leden'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '15201 Shady Grove Dr'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered 'Rockville'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 22:33:35
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
User entered empty.	(b) (4)	30 Oct 2020 21:01:14

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:51
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:21:26
User entered '20850'	System	20 Oct 2020 14:21:06

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:31:05
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
DataPoint Verified.	(b) (4)	30 Oct 2020 20:37:51
	(b) (4), (b) (6)	
User entered 'US'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:29:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	25 Mar 2021 14:03:43
User entered '4'	System	11 Nov 2020 20:33:13
User entered '3'	System	06 Nov 2020 18:33:44
Signature has been broken.	System	02 Nov 2020 21:31:20
User entered '2'	System	02 Nov 2020 21:31:20
User signature succeeded.	Mimi Van Der Leden	30 Oct 2020 21:01:39
	(b) (4)	
User entered '1'	System	20 Oct 2020 14:21:33

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:29:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:51:58
User entered '25/Mar/2021 10:03'	(b) (4) System	25 Mar 2021 14:03:43

US3952104

Folder: SAE USA-US215-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:29:57

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	08 Apr 2021 19:51:58
User entered '1'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:03:43