

US3952052 (Prod: Synexus - Optimal Research - Rockville)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:27:41

All time stamps listed in this document are displayed in GMT

US3952052

Form: Participant Creation

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

Participant ID

US3952052

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

US3952052

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	74
Age Units	YEARS
Age (Derived)	74
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Date of Informed Consent (<i>dd MMM yyyy</i>)	08 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

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 19:02:22

Generated On: 10 Jun 2021 10:27:41

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Condition	BASAL CELL SKIN CANCER
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1947
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1947
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1947
Start Year (derived)	1947
Stop Month and Year (derived)	JAN 1947
Stop Year (derived)	1947

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Condition	RADIAL KERATOTOMY
Start date (dd MMM yyyy)	UN UNK 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Condition	WISDOM TEETH REMOVAL
Start date (dd MMM yyyy)	UN UNK 1963
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1963
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1963
Start Year (derived)	1963
Stop Month and Year (derived)	JAN 1963
Stop Year (derived)	1963

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Condition	BILATERAL ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Condition	RADIAL KERATOTOMY
Start date (dd MMM yyyy)	UN UNK 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:17 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 09:17
Height (<i>xxx.x</i>)	65.0 in
Weight (<i>xxx.x</i>)	201.0 lb
BMI (<i>xxx.x</i>)	33.51809 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Date of assessment (dd MMM yyyy) 8 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1998

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:02:22

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:05:38

Generated On: 10 Jun 2021 10:27:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 19:05:38

Generated On: 10 Jun 2021 10:27:41

What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 189992

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 19:05:38

Generated On: 10 Jun 2021 10:27:41

Height	ND - Not Done
Weight	ND - Not Done

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:05:38

Generated On: 10 Jun 2021 10:27:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	09:17 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 09:17
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:05:38

Generated On: 10 Jun 2021 10:27:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	11:56 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:56
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 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 19:05:38

Generated On: 10 Jun 2021 10:27:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:05:38

Generated On: 10 Jun 2021 10:27:41

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 11:15 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 11:15

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 19:05:38

Generated On: 10 Jun 2021 10:27:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 SEP 2020

Collection time (00:00-23:59)

09:46 (24 HR)

Collection date and time (derived)

08 SEP 2020 09:46

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:48	08 SEP 2020 09:48
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:02:22

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:02

PC Open Date & Time

08 SEP 2020 11:35

PC Close Date & Time

08 SEP 2020 14:05

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	08 SEP 2020 19:59
PC Open Date & Time	08 SEP 2020 15:00
PC Close Date & Time	09 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

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

97.4 °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

09 SEP 2020 20:02

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

10 SEP 2020 19:52

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 20:04

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 20:37

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

13 SEP 2020 19:46

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 20:04

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 12:07

PC Open Date & Time

08 SEP 2020 11:35

PC Close Date & Time

08 SEP 2020 14:05

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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

08 SEP 2020 20:00

PC Open Date & Time

08 SEP 2020 15:00

PC Close Date & Time

09 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

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

09 SEP 2020 20:02

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

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

10 SEP 2020 19:52

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

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

11 SEP 2020 20:04

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

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

12 SEP 2020 20:37

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

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

13 SEP 2020 19:46

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

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

14 SEP 2020 20:05

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 12:08
PC Open Date & Time	08 SEP 2020 11:35
PC Close Date & Time	08 SEP 2020 14:05

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 20:02
PC Open Date & Time	08 SEP 2020 15:00
PC Close Date & Time	09 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2054

EAB) (1725)

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 20:03
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2054

EAB) (1725)

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:53
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2054

EAB) (1725)

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 20:05
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2054

EAB) (1725)

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 20:38
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

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

62 of 2054

EAB) (1725)

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:47
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

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

64 of 2054

EAB) (1725)

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 20:06
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3952052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:01:24

Generated On: 10 Jun 2021 10:27:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952052

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:01:24

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:01:24

Generated On: 10 Jun 2021 10:27:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952052

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:01:24

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:01:24

Generated On: 10 Jun 2021 10:27:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952052

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:01:24

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	13:49 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 13:49
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	15:49 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 15:49
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3952052

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

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.

US3952052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

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) 13 OCT 2020

What was the treatment time? (00:00-23:59) 15:06 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 15:06

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

What was the frequency of the study treatment dosing? ONCE

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

US3952052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

14:05 (24 HR)

Collection date and time (derived)

13 OCT 2020 14:05

US3952052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:00	13 OCT 2020 14:00
Nasopharyngeal Swab 2	No		

US3952052

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

13 OCT 2020 15:49

PC Open Date & Time

13 OCT 2020 15:26

PC Close Date & Time

13 OCT 2020 17:56

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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 96.3 °F

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

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

PC Time Stamp	13 OCT 2020 20:02
PC Open Date & Time	13 OCT 2020 18:51
PC Close Date & Time	14 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 19:23

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 06:41

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 16:45

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 12:02

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

18 OCT 2020 19:23

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 17:36

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 15:51

PC Open Date & Time

13 OCT 2020 15:26

PC Close Date & Time

13 OCT 2020 17:56

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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

13 OCT 2020 20:02

PC Open Date & Time

13 OCT 2020 18:51

PC Close Date & Time

14 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

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

14 OCT 2020 19:23

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

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

16 OCT 2020 06:42

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

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

16 OCT 2020 16:45

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

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

17 OCT 2020 12:02

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

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

18 OCT 2020 19:24

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

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

19 OCT 2020 17:36

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 15:51
PC Open Date & Time	13 OCT 2020 15:26
PC Close Date & Time	13 OCT 2020 17:56

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 20:03
PC Open Date & Time	13 OCT 2020 18:51
PC Close Date & Time	14 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2054

EAB) (1725)

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 19:24
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

102 of 2054

EAB) (1725)

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 06:41
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

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 ☒

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 16:46
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

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 ☒

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 12:03
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

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 ☒

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:24
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

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

110 of 2054

EAB) (1725)

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 17:37
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3952052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:01:24

Generated On: 10 Jun 2021 10:27:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952052

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:01:24

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:01:24

Generated On: 10 Jun 2021 10:27:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952052

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:01:24

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:01:24

Generated On: 10 Jun 2021 10:27:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952052

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:01:24

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

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) _____

US3952052

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

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.

US3952052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 NOV 2020

Collection time (00:00-23:59)

14:37 (24 HR)

Collection date and time (derived)

11 NOV 2020 14:37

US3952052

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:05:39

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 00:02:13
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 07:50:30

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 07:37:31
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 06:01:02
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 07:17:59
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 07:37:13
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

17 DEC 2020 07:54:37

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 07:12:21
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

31 DEC 2020 07:55:05

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

07 JAN 2021 07:53:16

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

16 JAN 2021 10:10:42

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

23 JAN 2021 06:43:26

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

28 JAN 2021 07:59:09

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

06 FEB 2021 07:00:19

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

18 FEB 2021 11:07:03

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 FEB 2021 11:55:21
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

05 MAR 2021 15:18:32

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 MAR 2021 05:36:15
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

18 MAR 2021 13:45:11

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

25 MAR 2021 15:44:43

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

02 APR 2021 07:54:58

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

08 APR 2021 07:01:56

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

15 APR 2021 11:26:18

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

22 APR 2021 06:29:51

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 08:10:05

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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°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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Patient Cloud Open Date & Time	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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°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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Date and time of submission

Patient Cloud Open Date & Time	20 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	24 OCT 2022 23:59
---	-------------------

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Date and time of submission

Patient Cloud Open Date & Time	10 NOV 2022 00:01
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Patient Cloud Close Date & Time	14 NOV 2022 23:59
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US3952052

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:27:41

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		01 MAR 2021 13:41:54

US3952052

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:41:29

Generated On: 10 Jun 2021 10:27:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952052

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:41:29

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:33:57

Generated On: 10 Jun 2021 10:27:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

ATTEMPTED CONTACT X3

If Contact Not Made, please provide Comments

US3952052

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:33:57

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:33:57

Generated On: 10 Jun 2021 10:27:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952052

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:33:57

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:33:57

Generated On: 10 Jun 2021 10:27:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952052

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:33:57

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 19:33:57

Generated On: 10 Jun 2021 10:27:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 19:33:57

Generated On: 10 Jun 2021 10:27:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 APR 2021
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	07 APR 2021 10:37
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952052

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 19:33:57

Generated On: 10 Jun 2021 10:27:41

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.

US3952052

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 19:33:57

Generated On: 10 Jun 2021 10:27:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 APR 2021

Collection time (00:00-23:59)

10:47 (24 HR)

Collection date and time (derived)

07 APR 2021 10:47

US3952052

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:33:57

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952052

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3952052

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:27:41

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3952052

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

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 19:33:56

Generated On: 10 Jun 2021 10:27:41

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

Visit date (dd MMM yyyy)	24 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3952052

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 19:33:56

Generated On: 10 Jun 2021 10:27:41

Date of updated informed consent (dd MMM yyyy) 24 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 24 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3952052

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 19:33:56

Generated On: 10 Jun 2021 10:27:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 FEB 2021

Collection time (00:00-23:59)

14:58 (24 HR)

Collection date and time (derived)

24 FEB 2021 14:58

US3952052

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Apr 2021 19:33:56

Generated On: 10 Jun 2021 10:27:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 FEB 2021
Collection time (00:00 - 23:59)	15:00
Collection Date and Time (derived)	24 FEB 2021 15:00

US3952052

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 19:08:18

Generated On: 10 Jun 2021 10:27:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

AEID	USA-US215-2021-MRNA-1273-P30 1000005
Adverse event	DIARRHEA FROM GIARDIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	06 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	08 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input checked="" type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

SUBJECT EXPERIENCED AE OF
"TRAVELER'S DIARRHEA
BEGINNING 09FEB2021. AFTER
"30 DAYS OF DIARRHEA" SHE
WENT TO THE HOSPITAL AND
WAS ADMITTED ON
06MAR2021. DURING
HOSPITALIZATION A BLOOD
CLOT ON (R) LUNG WAS
DISCOVERED PER SUBJECT
ACCOUNT.

FOUND TO HAVE GIARDIA
DIARRHEA AND TREATED
WITH METRONIDAZOLE. FOR
BLOOD CLOT WAS GIVEN
LOVENOX INJECTIONS.

DISCHARGED HOME ON
08MARCH2021 CONTINUING
ABOVE MEDS. HAD FOLLOW
UP WITH MD SCHEDULED FOR
09MAR2021.

FURTHER DETAILS WILL BE
PROVIDED UPON RECEIPT OF
MEDICAL RECORDS.

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

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

AEID	USA-US215-2021-MRNA-1273-P30 1000005
Adverse event	(R) PULMONARY EMBOLISM
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	06 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	08 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input checked="" type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	DURING HOSPITALIZATION FOR GIARDIA DIARRHEA A (R) PULMONARY EMBOLISM WAS DISCOVERED. SUBJECT WAS STARTED ON LOVENOX UNTIL 13MAR2021. BEGAN PRADAXA 150 MG BID ON 14MAR2021. MEDICAL RECORDS PENDING.
Serious Adverse Event Derived (CSA Programming Field Only)	1

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

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

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 19:33:56

Generated On: 10 Jun 2021 10:27:41

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

Yes ☒

No ☐

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

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

Name of Medication BYDUREON

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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Name of Medication GLIPIZIDE

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2012
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 19 JAN 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 19:33:53

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA 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 (4)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

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 (5)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 FEB 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		03 FEB 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 19:33:53

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Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 2500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 19:33:53

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Name of Medication FENOFIBRATE

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 145

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 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication TRAVELER'S DIARRHEA

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 (10)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	26 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 19:33:53

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Name of Medication ENOXAPARIN SODIUM
INJECTION

Prophylaxis Yes ☐
No ☒

Indication RIGHT PULMONARY
EMBOLISM

Dose per administration 8

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication DIARRHEA FROM GIARDIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

Name of Medication PRADAXA

Prophylaxis Yes ☐
No ☒

Indication RIGHT PULMONARY
EMBOLISM

Dose per administration 150

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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US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 19:33:53

Generated On: 10 Jun 2021 10:27:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3952052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 19:33:56

Generated On: 10 Jun 2021 10:27:41

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3952052

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:27:41

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3952052

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:27:41

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 ☐

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 19:33:56

Generated On: 10 Jun 2021 10:27:41

SAEID	USA-US215-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 19:33:56

Generated On: 10 Jun 2021 10:27:41

SAEID	USA-US215-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	11/MAR/2021 08:19
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

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 19:33:56

Generated On: 10 Jun 2021 10:27:41

SAEID	USA-US215-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	17/MAR/2021 10:53
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

US3952052 (Prod: Synexus - Optimal Research - Rockville)

US3952052

Form: Participant Creation

Generated On: 10 Jun 2021 10:27:41

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'US3952052'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:29:31

US3952052

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	22 Sep 2020 20:15:03

US3952052

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User closed query 'Per CDM: Please complete all applicable forms for this visit. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:12:28
Query 'Per CDM: Please complete all applicable forms for this visit. Thank you.' answered with 'all forms updated' (Site from DM).	Nick Bart (b) (4)	25 Sep 2020 15:17:03
User opened query 'Per CDM: Please complete all applicable forms for this visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 09:16:03
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:29:32

US3952052

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Clinic (Clinic)'	Stephanie Melton (b) (4)	22 Sep 2020 20:15:03

US3952052

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'SCRN'	System	22 Sep 2020 20:15:03

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered (b) (6) 1945'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:29:33

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '74'	Nick Bart	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'YEARS'	System	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '74'	System	08 Sep 2020 15:59:09

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Female (F)'	Nick Bart (b) (4)	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Nick Bart (b) (4)	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'I'	Nick Bart	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	(b) (4) Nick Bart (b) (4)	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:27:41

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	17 Sep 2020 20:31:22

US3952052

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:27:41

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '08 Sep 2020'	(b) (4) Atanas Filev (b) (4) (b) (4)	08 Sep 2020 15:59:09

US3952052

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Sep 2020'	System	08 Sep 2020 15:59:09

US3952052

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '2020'	System	08 Sep 2020 15:59:09

US3952052

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:27:41

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Amendment 2 (2)'	Atanas Filev (b) (4)	08 Sep 2020 15:59:09

US3952052

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	08 Sep 2020 15:59:09

US3952052

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	08 Sep 2020 15:59:09

US3952052

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:27:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	08 Sep 2020 15:59:09

US3952052

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:27:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	08 Sep 2020 15:59:09

US3952052

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:27:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:29:32

US3952052

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:27:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'I'	System	08 Sep 2020 15:59:12

US3952052

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	08 Sep 2020 15:59:12

US3952052

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:27:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Yes (Y)'	Nick Bart	25 Sep 2020 12:54:38

US3952052

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:27:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 12:55:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 12:55:53
Data point term sent to Coder	System	25 Sep 2020 12:55:26
User entered 'type ii diabetes'	Nick Bart (b) (4)	25 Sep 2020 12:54:52

US3952052

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 2012'	Nick Bart	25 Sep 2020 12:54:52

US3952052

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:54:52

US3952052

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:27:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:54:52

US3952052

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:54:52

US3952052

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:27:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:54:52

US3952052

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 2012'	System	25 Sep 2020 12:54:52

US3952052

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '2012'	System	25 Sep 2020 12:54:52

US3952052

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered empty.	System	25 Sep 2020 12:54:52

US3952052

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered empty.	System	25 Sep 2020 12:54:52

US3952052

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:27:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal tear, LLT: Retinal tear - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Sep 2020 08:12:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 08:12:17
Data point term sent to Coder	System	25 Sep 2020 12:55:26
User entered 'right torn retina'	Nick Bart (b) (4)	25 Sep 2020 12:55:10

US3952052

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 2019'	Nick Bart	25 Sep 2020 12:55:10

US3952052

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:55:10

US3952052

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:27:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Yes (Y)'	Nick Bart	25 Sep 2020 12:55:10

US3952052

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:55:10

US3952052

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:27:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:55:10

US3952052

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 2019'	System	25 Sep 2020 12:55:10

US3952052

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '2019'	System	25 Sep 2020 12:55:10

US3952052

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered empty.	System	25 Sep 2020 12:55:10

US3952052

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered empty.	System	25 Sep 2020 12:55:10

US3952052

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:27:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 12:56:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 12:56:45
Data point term sent to Coder	System	25 Sep 2020 12:56:27
User entered 'basal cell skin cancer'	Nick Bart (b) (4)	25 Sep 2020 12:55:27

US3952052

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 1975'	Nick Bart	25 Sep 2020 12:55:27

US3952052

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:55:27

US3952052

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:27:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:55:27

US3952052

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 2015'	Nick Bart (b) (4)	25 Sep 2020 12:55:27

US3952052

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:27:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:55:27

US3952052

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 1975'	System	25 Sep 2020 12:55:27

US3952052

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '1975'	System	25 Sep 2020 12:55:27

US3952052

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 2015'	System	25 Sep 2020 12:55:27

US3952052

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '2015'	System	25 Sep 2020 12:55:27

US3952052

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:27:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 12:56:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 12:56:45
Data point term sent to Coder	System	25 Sep 2020 12:56:27
User entered 'hyperlipidemia'	Nick Bart (b) (4)	25 Sep 2020 12:55:39

US3952052

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 2012'	Nick Bart	25 Sep 2020 12:55:39

US3952052

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:55:39

US3952052

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:27:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Yes (Y)'	Nick Bart	25 Sep 2020 12:55:39

US3952052

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:55:39

US3952052

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:27:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:55:39

US3952052

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 2012'	System	25 Sep 2020 12:55:39

US3952052

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '2012'	System	25 Sep 2020 12:55:39

US3952052

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered empty.	System	25 Sep 2020 12:55:39

US3952052

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered empty.	System	25 Sep 2020 12:55:39

US3952052

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:27:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 12:56:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 12:56:45
Data point term sent to Coder	System	25 Sep 2020 12:56:28
User entered 'tonsillectomy'	Nick Bart (b) (4)	25 Sep 2020 12:55:55

US3952052

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 1947'	Nick Bart	25 Sep 2020 12:55:55

US3952052

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:55:55

US3952052

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:27:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:55:55

US3952052

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 1947'	Nick Bart	25 Sep 2020 12:55:55

US3952052

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:27:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:55:55

US3952052

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 1947'	System	25 Sep 2020 12:55:55

US3952052

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '1947'	System	25 Sep 2020 12:55:55

US3952052

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 1947'	System	25 Sep 2020 12:55:55

US3952052

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '1947'	System	25 Sep 2020 12:55:55

US3952052

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:27:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratotomy, LLT: Keratotomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 12:58:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 12:58:48
Data point term sent to Coder	System	25 Sep 2020 12:57:29
User entered 'Radial keratotomy'	Nick Bart (b) (4)	25 Sep 2020 12:56:35

US3952052

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 1982'	Nick Bart	25 Sep 2020 12:56:35

US3952052

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:56:35

US3952052

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:27:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:56:35

US3952052

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 1982'	Nick Bart	25 Sep 2020 12:56:35

US3952052

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:27:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:56:35

US3952052

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 1982'	System	25 Sep 2020 12:56:35

US3952052

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '1982'	System	25 Sep 2020 12:56:35

US3952052

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 1982'	System	25 Sep 2020 12:56:35

US3952052

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '1982'	System	25 Sep 2020 12:56:35

US3952052

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:27:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 12:58:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 12:58:49
Data point term sent to Coder	System	25 Sep 2020 12:57:29
User entered 'complete hysterectomy'	Nick Bart (b) (4)	25 Sep 2020 12:56:55

US3952052

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 1998'	Nick Bart	25 Sep 2020 12:56:55

US3952052

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:56:55

US3952052

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:27:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	Nick Bart	25 Sep 2020 12:56:55

US3952052

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 1998'	Nick Bart	25 Sep 2020 12:56:55

US3952052

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:27:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:56:55

US3952052

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 1998'	System	25 Sep 2020 12:56:55

US3952052

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '1998'	System	25 Sep 2020 12:56:55

US3952052

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 1998'	System	25 Sep 2020 12:56:55

US3952052

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '1998'	System	25 Sep 2020 12:56:55

US3952052

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:27:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 22:00:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 22:00:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 13:00:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 13:00:47
Data point term sent to Coder	System	25 Sep 2020 12:59:36
User entered 'bilateral cataract surgery'	Nick Bart (b) (4)	25 Sep 2020 12:59:05

US3952052

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 2015'	Nick Bart	25 Sep 2020 12:59:05

US3952052

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:59:05

US3952052

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:27:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:59:05

US3952052

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 2015'	Nick Bart (b) (4)	25 Sep 2020 12:59:05

US3952052

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:27:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:59:05

US3952052

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 2015'	System	25 Sep 2020 12:59:05

US3952052

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '2015'	System	25 Sep 2020 12:59:05

US3952052

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 2015'	System	25 Sep 2020 12:59:05

US3952052

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '2015'	System	25 Sep 2020 12:59:05

US3952052

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:27:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Wisdom teeth removal, LLT: Wisdom teeth removal - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 13:00:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 13:00:46
Data point term sent to Coder	System	25 Sep 2020 12:59:36
User entered 'wisdom teeth removal'	Nick Bart (b) (4)	25 Sep 2020 12:59:33

US3952052

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 1963'	Nick Bart	25 Sep 2020 12:59:33

US3952052

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:59:33

US3952052

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:27:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	Nick Bart	25 Sep 2020 12:59:33

US3952052

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 1963'	Nick Bart (b) (4)	25 Sep 2020 12:59:33

US3952052

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:27:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:59:33

US3952052

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 1963'	System	25 Sep 2020 12:59:33

US3952052

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '1963'	System	25 Sep 2020 12:59:33

US3952052

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 1963'	System	25 Sep 2020 12:59:33

US3952052

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '1963'	System	25 Sep 2020 12:59:33

US3952052

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:27:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 13:01:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 13:01:45
Data point term sent to Coder	System	25 Sep 2020 13:00:37
User entered 'bilateral rotator cuff repair'	Nick Bart (b) (4)	25 Sep 2020 12:59:54

US3952052

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 2017'	Nick Bart	25 Sep 2020 12:59:54

US3952052

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:59:54

US3952052

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:27:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	Nick Bart	25 Sep 2020 12:59:54

US3952052

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 2017'	Nick Bart (b) (4)	25 Sep 2020 12:59:54

US3952052

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:27:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 12:59:54

US3952052

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 2017'	System	25 Sep 2020 12:59:54

US3952052

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '2017'	System	25 Sep 2020 12:59:54

US3952052

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 2017'	System	25 Sep 2020 12:59:54

US3952052

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '2017'	System	25 Sep 2020 12:59:54

US3952052

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:27:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratotomy, LLT: Keratotomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 13:01:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 13:01:45
Data point term sent to Coder	System	25 Sep 2020 13:00:37
User entered 'Radial keratotomy'	Nick Bart (b) (4)	25 Sep 2020 13:00:25

US3952052

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 1984'	Nick Bart	25 Sep 2020 13:00:25

US3952052

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 13:00:25

US3952052

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:27:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	Nick Bart	25 Sep 2020 13:00:25

US3952052

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 1984'	Nick Bart (b) (4)	25 Sep 2020 13:00:25

US3952052

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:27:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 13:00:25

US3952052

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 1984'	System	25 Sep 2020 13:00:25

US3952052

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '1984'	System	25 Sep 2020 13:00:25

US3952052

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 1984'	System	25 Sep 2020 13:00:25

US3952052

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '1984'	System	25 Sep 2020 13:00:25

US3952052

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:27:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 13:01:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 13:01:45
Data point term sent to Coder	System	25 Sep 2020 13:00:37
User entered 'obesity'	Nick Bart (b) (4)	25 Sep 2020 13:00:37

US3952052

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'un UNK 1994'	Nick Bart	25 Sep 2020 13:00:37

US3952052

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 13:00:37

US3952052

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:27:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Yes (Y)'	Nick Bart	25 Sep 2020 13:00:37

US3952052

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:00:37

US3952052

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:27:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Nick Bart	25 Sep 2020 13:00:37

US3952052

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'Jan 1994'	System	25 Sep 2020 13:00:37

US3952052

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '1994'	System	25 Sep 2020 13:00:37

US3952052

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered empty.	System	25 Sep 2020 13:00:37

US3952052

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered empty.	System	25 Sep 2020 13:00:37

US3952052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	22 Sep 2020 20:17:55

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Nick Bart (b) (4)	04 Jan 2021 17:43:33
User entered '8 Sep 2020'	Stephanie Melton (b) (4)	22 Sep 2020 20:17:55
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '09:17'	Stephanie Melton (b) (4)	22 Sep 2020 20:17:55

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '08 Sep 2020 09:17'	System	04 Jan 2021 17:43:33
User entered '8 Sep 2020 09:17'	System	22 Sep 2020 20:17:55

US3952052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '65.0' in reason for change: Data Entry Error	(b) (4)	
	Nick Bart (b) (4)	04 Jan 2021 17:43:41
User entered '65' in	Stephanie Melton (b) (4)	22 Sep 2020 20:17:55
DataPoint set to visible.	(b) (4)	
	System	08 Sep 2020 15:59:12

US3952052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '201.0' lb reason for change: Data Entry Error	(b) (4)	
	Nick Bart (b) (4)	04 Jan 2021 17:43:41
User entered '201' lb	Stephanie Melton (b) (4)	22 Sep 2020 20:17:55
DataPoint set to visible.	(b) (4)	
	System	08 Sep 2020 15:59:12

US3952052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered '33.51809'	System	22 Sep 2020 20:17:55
DataPoint set to visible.	System	08 Sep 2020 15:59:12

US3952052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'kg/m2'	System	22 Sep 2020 20:17:55
DataPoint set to visible.	System	08 Sep 2020 15:59:12

US3952052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User closed query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, 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. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 06:18:30
Query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, 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. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 17:43:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	04 Jan 2021 17:43:25
User opened query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, 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. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:16:55
User entered '36.9' C	Stephanie Melton (b) (4) (b) (4)	22 Sep 2020 20:17:55

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty; reason for change Data Entry Error	(b) (4) Nick Bart (b) (4)	04 Jan 2021 17:43:25
User entered 'Oral (Oral)'	Stephanie Melton (b) (4) (b) (4)	22 Sep 2020 20:17:55

US3952052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	Stephanie Melton (b) (4)	22 Sep 2020 20:17:55

US3952052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Jan 2021 17:43:25
User entered '82'	Nick Bart (b) (4)	04 Jan 2021 17:43:25
	Stephanie Melton (b) (4)	22 Sep 2020 20:17:55
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'bpm'	System	22 Sep 2020 20:17:55

US3952052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Jan 2021 17:43:25
User entered '12'	Nick Bart (b) (4)	22 Sep 2020 20:17:55
	Stephanie Melton (b) (4)	
	(b) (4)	

US3952052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'breaths/min'	System	22 Sep 2020 20:17:55

US3952052

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Jan 2021 17:43:25
User entered '128'	Nick Bart (b) (4)	22 Sep 2020 20:17:55
	Stephanie Melton (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'mmHg'	System	22 Sep 2020 20:17:55

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Jan 2021 17:43:25
User entered '73'	Nick Bart (b) (4)	04 Jan 2021 17:43:25
	Stephanie Melton (b) (4)	22 Sep 2020 20:17:55
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User entered 'mmHg'	System	22 Sep 2020 20:17:55

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:27:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	22 Sep 2020 20:18:23

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:27:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '8 Sep 2020'	Stephanie Melton (b) (4)	22 Sep 2020 20:18:23

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:27:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '8 Sep 2020'	Stephanie Melton (b) (4)	22 Sep 2020 20:19:32

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:27:41

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	22 Sep 2020 20:19:32

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:27:41

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Surgically sterile (SURGICALLY STERILE)'	Stephanie Melton (b) (4)	22 Sep 2020 20:19:32

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:27:41

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	Stephanie Melton (b) (4)	22 Sep 2020 20:19:32

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User closed query 'Date of surgery is provided, however, date of surgery unknown is checked. Please correct.' (Site from System).	(b) (4)	22 Sep 2020 20:19:48
User opened query 'Date of surgery is provided, however, date of surgery unknown is checked. Please correct.' (Site from System).	System	22 Sep 2020 20:19:32
User entered 'UN UNK 1998'	Stephanie Melton (b) (4)	22 Sep 2020 20:19:32
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:27:41

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Stephanie Melton	(b) (4) 22 Sep 2020 20:19:48
User entered '1'	(b) (4)	
	Stephanie Melton	(b) (4) 22 Sep 2020 20:19:32
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	(b) (4)	22 Sep 2020 20:19:32

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:27:41

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Stephanie Melton (b) (4)	22 Sep 2020 20:19:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	(b) (4)	22 Sep 2020 20:21:10
	Stephanie Melton (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	(b) (4)	22 Sep 2020 20:21:10
	Stephanie Melton (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	Stephanie Melton	22 Sep 2020 20:21:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	Stephanie Melton	22 Sep 2020 20:21:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	(b) (4)	22 Sep 2020 20:21:10
	Stephanie Melton (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	Stephanie Melton (b) (4)	22 Sep 2020 20:21:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	Stephanie Melton (b) (4)	22 Sep 2020 20:21:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	Stephanie Melton (b) (4)	22 Sep 2020 20:21:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

[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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	(b) (4)	22 Sep 2020 20:21:10
	Stephanie Melton (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	Stephanie Melton (b) (4)	22 Sep 2020 20:21:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	Stephanie Melton (b) (4)	22 Sep 2020 20:21:10

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	(b) (4)	22 Sep 2020 20:21:10
	Stephanie Melton (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	(b) (4)	22 Sep 2020 20:21:10
	Stephanie Melton (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'I'	Stephanie Melton (b) (4)	22 Sep 2020 20:21:10

US3952052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	(b) (4)	22 Sep 2020 20:21:10
	Stephanie Melton (b) (4)	
	(b) (4)	

US3952052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Stephanie Melton (b) (4)	22 Sep 2020 20:21:10

US3952052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

[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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	(b) (4) Stephanie Melton (b) (4) (b) (4)	22 Sep 2020 20:21:10

US3952052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

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 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Stephanie Melton (b) (4)	22 Sep 2020 20:21:10

US3952052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Stephanie Melton (b) (4)	22 Sep 2020 20:21:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '0'	Stephanie Melton (b) (4)	22 Sep 2020 20:21:10

US3952052

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:27:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:30:40
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	(b) (4)	22 Sep 2020 20:21:10
	Stephanie Melton (b) (4)	
	(b) (4)	

US3952052

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:53:49

US3952052

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '08 Sep 2020'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:53:49

US3952052

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[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 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:53:49

US3952052

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'VISIT1'	System	25 Sep 2020 12:53:49

US3952052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 14:39:27

US3952052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '189992'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 14:39:27

US3952052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 14:39:27

US3952052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:27:41

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 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:01:18

US3952052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:27:41

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 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'No (N)'	Nick Bart	25 Sep 2020 13:01:18

US3952052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:01:18

US3952052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:01:18

US3952052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:27:41

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:01:18

US3952052

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:01:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:07:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:36:22

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:27:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User closed query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 06:18:56
Query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 17:43:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	04 Jan 2021 17:43:55
User opened query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:17:11
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:27:41

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Jan 2021 17:43:55
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:27:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User closed query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 06:18:56
Query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 17:43:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	04 Jan 2021 17:43:55
User opened query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:17:11
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:27:41

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Jan 2021 17:43:55
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User closed query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, 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)	05 Jan 2021 06:20:08
Query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, 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)	04 Jan 2021 17:44:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4)	04 Jan 2021 17:44:40
User opened query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, 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)	05 Oct 2020 14:18:25
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	04 Jan 2021 17:44:40
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '09:17' reason for change: Data Entry Error	(b) (4)	04 Jan 2021 17:44:40
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered '08 Sep 2020 09:17'	System	04 Jan 2021 17:44:40
User entered empty.	System	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '36.9' C reason for change: Data Entry Error	(b) (4)	04 Jan 2021 17:44:40
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	04 Jan 2021 17:44:40
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '82' reason for change: Data Entry Error	(b) (4)	04 Jan 2021 17:44:40
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'bpm'	System	04 Jan 2021 17:44:40
User entered empty.	System	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '12' reason for change: Data Entry Error	(b) (4)	04 Jan 2021 17:44:40
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'breaths/min'	System	04 Jan 2021 17:44:40
User entered empty.	System	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '128' reason for change: Data Entry Error	(b) (4)	04 Jan 2021 17:44:40
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'mmHg'	System	04 Jan 2021 17:44:40
User entered empty.	System	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '73' reason for change: Data Entry Error	(b) (4)	04 Jan 2021 17:44:40
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'mmHg'	System	04 Jan 2021 17:44:40
User entered empty.	System	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:27:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User closed query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 06:18:56
Query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 17:43:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	04 Jan 2021 17:43:55
User opened query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:17:11
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:27:41

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Jan 2021 17:43:55
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '08 Sep 2020'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '11:56'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered '08 Sep 2020 11:56'	System	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '36.9' C	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '75'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'bpm'	System	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '16'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'breaths/min'	System	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '115'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'mmHg'	System	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '69'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'mmHg'	System	25 Sep 2020 13:02:25

US3952052

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:27:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:53:57

US3952052

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:27:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '08 Sep 2020'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:53:57

US3952052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	08 Sep 2020 15:59:51

US3952052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	08 Sep 2020 15:59:51

US3952052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

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 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	08 Sep 2020 15:59:51

US3952052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 15:59:51

US3952052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '08 Sep 2020'	(b) (4) Atanas Filev (b) (4) (b) (4)	08 Sep 2020 15:59:51

US3952052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '11:15'	(b) (4) Atanas Filev (b) (4) (b) (4)	08 Sep 2020 15:59:51

US3952052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered '08 Sep 2020 11:15'	System	08 Sep 2020 15:59:51

US3952052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) Atanas Filev (b) (4) (b) (4)	08 Sep 2020 15:59:51

US3952052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'ONCE'	System	08 Sep 2020 15:59:51

US3952052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 15:59:51

US3952052

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:01:42

US3952052

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '08 Sep 2020'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:01:42

US3952052

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '09:46'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:01:42

US3952052

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered '08 Sep 2020 09:46'	System	25 Sep 2020 13:01:42

US3952052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:27:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '08 Sep 2020'	Nick Bart	25 Sep 2020 13:01:54

US3952052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:27:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4)	25 Sep 2020 13:01:54

US3952052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:27:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:01:54

US3952052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:27:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered '09:48'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:01:54

US3952052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered '08 Sep 2020 09:48'	System	25 Sep 2020 13:01:54

US3952052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:27:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4)	25 Sep 2020 13:01:54

US3952052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:27:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:01:54

US3952052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:01:54

US3952052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered empty.	System	25 Sep 2020 13:01:54

US3952052

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:02:22
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 12:54:04

US3952052

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'I'	System	25 Sep 2020 12:54:04

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:02:01', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '2801a7a1-5497-407d-a002-206474a6f91c' User entered 'Yes (Y)'	System	08 Sep 2020 16:03:27
	System	08 Sep 2020 16:03:27

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:02:15', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '2801a7a1-5497-407d-a002-206474a6f91c' User entered '98.4'	System	08 Sep 2020 16:03:27
	System	08 Sep 2020 16:03:27

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:02:21', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '2801a7a1-5497-407d-a002-206474a6f91c' User entered 'No (N)'	System	08 Sep 2020 16:03:27
	System	08 Sep 2020 16:03:27

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:02:32', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '2801a7a1-5497-407d-a002-206474a6f91c' User entered '08 Sep 2020 12:02'	System	08 Sep 2020 16:03:27
	System	08 Sep 2020 16:03:27

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '08 Sep 2020 11:35'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '08 Sep 2020 14:05'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T19:59:14', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '50bd21c3-6d86-44cf-bb29-561c64d87991' User entered 'Yes (Y)'	System	09 Sep 2020 00:00:07
	System	09 Sep 2020 00:00:07

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T19:59:33', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '50bd21c3-6d86-44cf-bb29-561c64d87991' User entered '97.4'	System	09 Sep 2020 00:00:07
	System	09 Sep 2020 00:00:07

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T19:59:37', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '50bd21c3-6d86-44cf-bb29-561c64d87991'	System	09 Sep 2020 00:00:07
User entered 'No (N)'	System	09 Sep 2020 00:00:07

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T19:59:58', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '50bd21c3-6d86-44cf-bb29-561c64d87991' User entered '08 Sep 2020 19:59'	System	09 Sep 2020 00:00:07
	System	09 Sep 2020 00:00:07

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '08 Sep 2020 15:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 2'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:01:37', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '490d9545-8921-4e9f-b6ba-50d25cd742cd' User entered 'Yes (Y)'	System	10 Sep 2020 00:02:39
	System	10 Sep 2020 00:02:39

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:02:20', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '490d9545-8921-4e9f-b6ba-50d25cd742cd' User entered '97.4'	System	10 Sep 2020 00:02:39
	System	10 Sep 2020 00:02:39

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:02:30', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '490d9545-8921-4e9f-b6ba-50d25cd742cd' User entered 'No (N)'	System	10 Sep 2020 00:02:39
	System	10 Sep 2020 00:02:39

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:02:35', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '490d9545-8921-4e9f-b6ba-50d25cd742cd' User entered '09 Sep 2020 20:02'	System	10 Sep 2020 00:02:39
	System	10 Sep 2020 00:02:39

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 3'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '17de8aaf-fac2-4fb0-85c5-cbeae2e2e6d0'	System	10 Sep 2020 23:52:23
User entered 'Yes (Y)'	System	10 Sep 2020 23:52:23

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:06', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '17de8aaf-fac2-4fb0-85c5-cbeae2e2e6d0'	System	10 Sep 2020 23:52:23
User entered '98.0'	System	10 Sep 2020 23:52:23

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:11', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '17de8aaf-fac2-4fb0-85c5-cbeae2e2e6d0'	System	10 Sep 2020 23:52:23
User entered 'No (N)'	System	10 Sep 2020 23:52:23

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:20', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '17de8aaf-fac2-4fb0-85c5-cbeae2e2e6d0' User entered '10 Sep 2020 19:52'	System	10 Sep 2020 23:52:23
	System	10 Sep 2020 23:52:23

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 4'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:04:21', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e84e11ea-8803-460a-91b6-a5ac7fb14ef6'	System	12 Sep 2020 00:04:37
User entered 'Yes (Y)'	System	12 Sep 2020 00:04:37

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:04:27', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e84e11ea-8803-460a-91b6-a5ac7fb14ef6' User entered '98.5'	System	12 Sep 2020 00:04:37
	System	12 Sep 2020 00:04:37

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:04:30', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e84e11ea-8803-460a-91b6-a5ac7fb14ef6'	System	12 Sep 2020 00:04:37
User entered 'No (N)'	System	12 Sep 2020 00:04:37

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:04:34', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e84e11ea-8803-460a-91b6-a5ac7fb14ef6'	System	12 Sep 2020 00:04:37
User entered '11 Sep 2020 20:04'	System	12 Sep 2020 00:04:37

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 5'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:18', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '09afe45f-cffc-4fb2-aab4-4805efd13ebc' User entered 'Yes (Y)'	System	13 Sep 2020 00:37:34
	System	13 Sep 2020 00:37:34

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:24', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '09afe45f-cffc-4fb2-aab4-4805efd13ebc' User entered '97.7'	System	13 Sep 2020 00:37:34
	System	13 Sep 2020 00:37:34

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:28', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '09afe45f-cffc-4fb2-aab4-4805efd13ebc'	System	13 Sep 2020 00:37:34
User entered 'No (N)'	System	13 Sep 2020 00:37:34

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:32', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '09afe45f-cffc-4fb2-aab4-4805efd13ebc'	System	13 Sep 2020 00:37:34
User entered '12 Sep 2020 20:37'	System	13 Sep 2020 00:37:34

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 6'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:46:24', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'aad63851-03a2-4e89-831d-6d32e3c7b68c' User entered 'Yes (Y)'	System	13 Sep 2020 23:46:41
	System	13 Sep 2020 23:46:41

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:46:31', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'aad63851-03a2-4e89-831d-6d32e3c7b68c' User entered '97.6'	System	13 Sep 2020 23:46:41
	System	13 Sep 2020 23:46:41

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:46:34', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'aad63851-03a2-4e89-831d-6d32e3c7b68c' User entered 'No (N)'	System	13 Sep 2020 23:46:41
	System	13 Sep 2020 23:46:41

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:46:39', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'aad63851-03a2-4e89-831d-6d32e3c7b68c' User entered '13 Sep 2020 19:46'	System	13 Sep 2020 23:46:41
	System	13 Sep 2020 23:46:41

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 7'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:04:20', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '20a2ebd8-e0b9-4521-8202-3050f9266936' User entered 'Yes (Y)'	System	15 Sep 2020 00:04:38
	System	15 Sep 2020 00:04:38

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:04:26', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '20a2ebd8-e0b9-4521-8202-3050f9266936' User entered '97.6'	System	15 Sep 2020 00:04:38
	System	15 Sep 2020 00:04:38

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:04:29', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '20a2ebd8-e0b9-4521-8202-3050f9266936' User entered 'No (N)'	System	15 Sep 2020 00:04:38
	System	15 Sep 2020 00:04:38

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:04:35', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '20a2ebd8-e0b9-4521-8202-3050f9266936' User entered '14 Sep 2020 20:04'	System	15 Sep 2020 00:04:38
	System	15 Sep 2020 00:04:38

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:05:06', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ff7106d2-1d4b-495d-bba8-a51bdf48680f' User entered 'None (1)'	System	08 Sep 2020 16:07:37
	System	08 Sep 2020 16:07:37

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:06:50', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ff7106d2-1d4b-495d-bba8-a51bdf48680f' User entered 'No (N)'	System	08 Sep 2020 16:07:37
	System	08 Sep 2020 16:07:37

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:06:56', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ff7106d2-1d4b-495d-bba8-a51bdf48680f' User entered 'No (N)'	System	08 Sep 2020 16:07:37
	System	08 Sep 2020 16:07:37

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:07:14', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ff7106d2-1d4b-495d-bba8-a51bdf48680f' User entered 'None (1)'	System	08 Sep 2020 16:07:37
	System	08 Sep 2020 16:07:37

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:07:33', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ff7106d2-1d4b-495d-bba8-a51bdf48680f' User entered '08 Sep 2020 12:07'	System	08 Sep 2020 16:07:37
	System	08 Sep 2020 16:07:37

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '08 Sep 2020 11:35'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '08 Sep 2020 14:05'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:00:06', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ea515410-a3ac-4565-82bc-8ffe0aa1c921'	System	09 Sep 2020 00:00:46
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 00:00:46

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:00:10', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ea515410-a3ac-4565-82bc-8ffe0aa1c921' User entered 'No (N)'	System	09 Sep 2020 00:00:46
	System	09 Sep 2020 00:00:46

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:00:27', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ea515410-a3ac-4565-82bc-8ffe0aa1c921' User entered 'No (N)'	System	09 Sep 2020 00:00:46
	System	09 Sep 2020 00:00:46

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:00:32', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ea515410-a3ac-4565-82bc-8ffe0aa1c921'	System	09 Sep 2020 00:00:46
User entered 'None (1)'	System	09 Sep 2020 00:00:46

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:00:44', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ea515410-a3ac-4565-82bc-8ffe0aa1c921'	System	09 Sep 2020 00:00:46
User entered '08 Sep 2020 20:00'	System	09 Sep 2020 00:00:46

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '08 Sep 2020 15:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 2'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:02:41', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '6ca03b39-b8c2-4295-9ce6-137ab374d942'	System	10 Sep 2020 00:03:00
User entered 'None (1)'	System	10 Sep 2020 00:03:00

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:02:44', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '6ca03b39-b8c2-4295-9ce6-137ab374d942'	System	10 Sep 2020 00:03:00
User entered 'No (N)'	System	10 Sep 2020 00:03:00

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:02:47', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '6ca03b39-b8c2-4295-9ce6-137ab374d942'	System	10 Sep 2020 00:03:00
User entered 'No (N)'	System	10 Sep 2020 00:03:00

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:02:50', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '6ca03b39-b8c2-4295-9ce6-137ab374d942'	System	10 Sep 2020 00:03:00
User entered 'None (1)'	System	10 Sep 2020 00:03:00

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:02:57', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '6ca03b39-b8c2-4295-9ce6-137ab374d942'	System	10 Sep 2020 00:03:00
User entered '09 Sep 2020 20:02'	System	10 Sep 2020 00:03:00

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 3'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:28', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'a8cfdc14-c423-4c72-818d-a418e929a362'	System	10 Sep 2020 23:52:46
User entered 'None (1)'	System	10 Sep 2020 23:52:46

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:31', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'a8cfdc14-c423-4c72-818d-a418e929a362'	System	10 Sep 2020 23:52:46
User entered 'No (N)'	System	10 Sep 2020 23:52:46

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:34', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'a8cfdc14-c423-4c72-818d-a418e929a362' User entered 'No (N)'	System	10 Sep 2020 23:52:46
	System	10 Sep 2020 23:52:46

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:38', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'a8cfdc14-c423-4c72-818d-a418e929a362' User entered 'None (1)'	System	10 Sep 2020 23:52:46
	System	10 Sep 2020 23:52:46

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:45', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'a8cfdc14-c423-4c72-818d-a418e929a362' User entered '10 Sep 2020 19:52'	System	10 Sep 2020 23:52:46
	System	10 Sep 2020 23:52:46

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 4'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:04:40', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c0bba7d8-1028-4f86-9934-037c8396d7bc' User entered 'None (1)'	System	12 Sep 2020 00:04:54
	System	12 Sep 2020 00:04:54

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:04:42', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c0bba7d8-1028-4f86-9934-037c8396d7bc' User entered 'No (N)'	System	12 Sep 2020 00:04:54
	System	12 Sep 2020 00:04:54

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:04:44', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c0bba7d8-1028-4f86-9934-037c8396d7bc' User entered 'No (N)'	System	12 Sep 2020 00:04:54
	System	12 Sep 2020 00:04:54

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:04:47', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c0bba7d8-1028-4f86-9934-037c8396d7bc' User entered 'None (1)'	System	12 Sep 2020 00:04:54
	System	12 Sep 2020 00:04:54

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:04:52', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c0bba7d8-1028-4f86-9934-037c8396d7bc' User entered '11 Sep 2020 20:04'	System	12 Sep 2020 00:04:54
	System	12 Sep 2020 00:04:54

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 5'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:37', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '95465ad0-e57f-4e54-820f-c4b5055328e2' User entered 'None (1)'	System	13 Sep 2020 00:37:54
	System	13 Sep 2020 00:37:54

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:40', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '95465ad0-e57f-4e54-820f-c4b5055328e2' User entered 'No (N)'	System	13 Sep 2020 00:37:54
	System	13 Sep 2020 00:37:54

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:42', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '95465ad0-e57f-4e54-820f-c4b5055328e2' User entered 'No (N)'	System	13 Sep 2020 00:37:54
	System	13 Sep 2020 00:37:54

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:44', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '95465ad0-e57f-4e54-820f-c4b5055328e2' User entered 'None (1)'	System	13 Sep 2020 00:37:54
	System	13 Sep 2020 00:37:54

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:48', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '95465ad0-e57f-4e54-820f-c4b5055328e2' User entered '12 Sep 2020 20:37'	System	13 Sep 2020 00:37:54
	System	13 Sep 2020 00:37:54

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 6'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:46:44', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '891aea6b-6bc5-426a-abaf-cdc4424a9fe6' User entered 'None (1)'	System	13 Sep 2020 23:47:01
	System	13 Sep 2020 23:47:01

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:46:46', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '891aea6b-6bc5-426a-abaf-cdc4424a9fe6' User entered 'No (N)'	System	13 Sep 2020 23:47:01
	System	13 Sep 2020 23:47:01

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:46:48', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '891aea6b-6bc5-426a-abaf-cdc4424a9fe6' User entered 'No (N)'	System	13 Sep 2020 23:47:01
	System	13 Sep 2020 23:47:01

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:46:50', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '891aea6b-6bc5-426a-abaf-cdc4424a9fe6' User entered 'None (1)'	System	13 Sep 2020 23:47:01
	System	13 Sep 2020 23:47:01

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:46:58', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '891aea6b-6bc5-426a-abaf-cdc4424a9fe6' User entered '13 Sep 2020 19:46'	System	13 Sep 2020 23:47:01
	System	13 Sep 2020 23:47:01

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 7'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:04:42', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '64690fe9-c801-4d01-9f60-500b7e3052e3' User entered 'None (1)'	System	15 Sep 2020 00:05:10
	System	15 Sep 2020 00:05:10

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:04:47', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '64690fe9-c801-4d01-9f60-500b7e3052e3' User entered 'No (N)'	System	15 Sep 2020 00:05:10
	System	15 Sep 2020 00:05:10

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:04:50', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '64690fe9-c801-4d01-9f60-500b7e3052e3' User entered 'No (N)'	System	15 Sep 2020 00:05:10
	System	15 Sep 2020 00:05:10

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:04:53', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '64690fe9-c801-4d01-9f60-500b7e3052e3' User entered 'None (1)'	System	15 Sep 2020 00:05:10
	System	15 Sep 2020 00:05:10

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:05:03', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '64690fe9-c801-4d01-9f60-500b7e3052e3' User entered '14 Sep 2020 20:05'	System	15 Sep 2020 00:05:10
	System	15 Sep 2020 00:05:10

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:07:41', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ca146fea-e077-496c-903d-cade8d92aedic' User entered 'None (0)'	System	08 Sep 2020 16:08:01
	System	08 Sep 2020 16:08:01

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:07:44', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ca146fea-e077-496c-903d-cade8d92aedic' User entered 'None (0)'	System	08 Sep 2020 16:08:01
	System	08 Sep 2020 16:08:01

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:07:46', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ca146fea-e077-496c-903d-cade8d92aedic' User entered 'None (0)'	System	08 Sep 2020 16:08:01
	System	08 Sep 2020 16:08:01

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:07:48', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ca146fea-e077-496c-903d-cade8d92aedic' User entered 'None (0)'	System	08 Sep 2020 16:08:01
	System	08 Sep 2020 16:08:01

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:07:50', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ca146fea-e077-496c-903d-cade8d92aedic' User entered 'None (0)'	System	08 Sep 2020 16:08:01
	System	08 Sep 2020 16:08:01

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:07:52', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ca146fea-e077-496c-903d-cade8d92aedic' User entered 'None (0)'	System	08 Sep 2020 16:08:01
	System	08 Sep 2020 16:08:01

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:07:57', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ca146fea-e077-496c-903d-cade8d92aedic' User entered 'No (N)'	System	08 Sep 2020 16:08:01
	System	08 Sep 2020 16:08:01

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T12:08:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ca146fea-e077-496c-903d-cade8d92aedic' User entered '08 Sep 2020 12:08'	System	08 Sep 2020 16:08:01
	System	08 Sep 2020 16:08:01

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '08 Sep 2020 11:35'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '08 Sep 2020 14:05'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:01:23', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '393a54f9-d9e0-404e-a9a3-4ea997c59a2c'	System	09 Sep 2020 00:02:12
User entered 'No interference with activity (1)'	System	09 Sep 2020 00:02:12

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:01:29', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '393a54f9-d9e0-404e-a9a3-4ea997c59a2c' User entered 'None (0)'	System	09 Sep 2020 00:02:12
	System	09 Sep 2020 00:02:12

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:01:31', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '393a54f9-d9e0-404e-a9a3-4ea997c59a2c' User entered 'None (0)'	System	09 Sep 2020 00:02:12
	System	09 Sep 2020 00:02:12

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:01:34', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '393a54f9-d9e0-404e-a9a3-4ea997c59a2c' User entered 'None (0)'	System	09 Sep 2020 00:02:12
	System	09 Sep 2020 00:02:12

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:01:49', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '393a54f9-d9e0-404e-a9a3-4ea997c59a2c'	System	09 Sep 2020 00:02:12
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Sep 2020 00:02:12

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:01:52', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '393a54f9-d9e0-404e-a9a3-4ea997c59a2c' User entered 'None (0)'	System	09 Sep 2020 00:02:12
	System	09 Sep 2020 00:02:12

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:01:55', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '393a54f9-d9e0-404e-a9a3-4ea997c59a2c' User entered 'No (N)'	System	09 Sep 2020 00:02:12
	System	09 Sep 2020 00:02:12

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-08T20:02:09', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '393a54f9-d9e0-404e-a9a3-4ea997c59a2c' User entered '08 Sep 2020 20:02'	System	09 Sep 2020 00:02:12
	System	09 Sep 2020 00:02:12

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '08 Sep 2020 15:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 2'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:03:02', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f7b57eb4-404a-42a0-8423-aef418a2103a' User entered 'None (0)'	System	10 Sep 2020 00:03:38
	System	10 Sep 2020 00:03:38

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:03:10', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f7b57eb4-404a-42a0-8423-aef418a2103a'	System	10 Sep 2020 00:03:38
User entered 'No interference with activity (1)'	System	10 Sep 2020 00:03:38

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:03:13', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f7b57eb4-404a-42a0-8423-aef418a2103a' User entered 'None (0)'	System	10 Sep 2020 00:03:38
	System	10 Sep 2020 00:03:38

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:03:16', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f7b57eb4-404a-42a0-8423-aef418a2103a' User entered 'None (0)'	System	10 Sep 2020 00:03:38
	System	10 Sep 2020 00:03:38

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:03:18', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f7b57eb4-404a-42a0-8423-aef418a2103a' User entered 'None (0)'	System	10 Sep 2020 00:03:38
	System	10 Sep 2020 00:03:38

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:03:20', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f7b57eb4-404a-42a0-8423-aef418a2103a' User entered 'None (0)'	System	10 Sep 2020 00:03:38
	System	10 Sep 2020 00:03:38

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:03:24', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f7b57eb4-404a-42a0-8423-aef418a2103a' User entered 'No (N)'	System	10 Sep 2020 00:03:38
	System	10 Sep 2020 00:03:38

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-09T20:03:35', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f7b57eb4-404a-42a0-8423-aef418a2103a' User entered '09 Sep 2020 20:03'	System	10 Sep 2020 00:03:38
	System	10 Sep 2020 00:03:38

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 3'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:50', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '856551a3-c623-4acd-8110-08f226c1e6ed' User entered 'None (0)'	System	10 Sep 2020 23:53:16
	System	10 Sep 2020 23:53:16

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:53', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '856551a3-c623-4acd-8110-08f226c1e6ed' User entered 'None (0)'	System	10 Sep 2020 23:53:16
	System	10 Sep 2020 23:53:16

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:55', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '856551a3-c623-4acd-8110-08f226c1e6ed' User entered 'None (0)'	System	10 Sep 2020 23:53:16
	System	10 Sep 2020 23:53:16

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:52:58', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '856551a3-c623-4acd-8110-08f226c1e6ed' User entered 'None (0)'	System	10 Sep 2020 23:53:16
	System	10 Sep 2020 23:53:16

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:53:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '856551a3-c623-4acd-8110-08f226c1e6ed' User entered 'None (0)'	System	10 Sep 2020 23:53:16
	System	10 Sep 2020 23:53:16

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:53:03', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '856551a3-c623-4acd-8110-08f226c1e6ed' User entered 'None (0)'	System	10 Sep 2020 23:53:16
	System	10 Sep 2020 23:53:16

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:53:05', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '856551a3-c623-4acd-8110-08f226c1e6ed' User entered 'No (N)'	System	10 Sep 2020 23:53:16
	System	10 Sep 2020 23:53:16

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-10T19:53:14', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '856551a3-c623-4acd-8110-08f226c1e6ed' User entered '10 Sep 2020 19:53'	System	10 Sep 2020 23:53:16
	System	10 Sep 2020 23:53:16

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 4'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:04:57', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '34961a0e-0097-4609-bbce-63d16c83bdea' User entered 'None (0)'	System	12 Sep 2020 00:05:21
	System	12 Sep 2020 00:05:21

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:04:59', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '34961a0e-0097-4609-bbce-63d16c83bdea' User entered 'None (0)'	System	12 Sep 2020 00:05:21
	System	12 Sep 2020 00:05:21

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:05:01', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '34961a0e-0097-4609-bbce-63d16c83bdea' User entered 'None (0)'	System	12 Sep 2020 00:05:21
	System	12 Sep 2020 00:05:21

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:05:03', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '34961a0e-0097-4609-bbce-63d16c83bdea' User entered 'None (0)'	System	12 Sep 2020 00:05:21
	System	12 Sep 2020 00:05:21

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:05:05', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '34961a0e-0097-4609-bbce-63d16c83bdea' User entered 'None (0)'	System	12 Sep 2020 00:05:21
	System	12 Sep 2020 00:05:21

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:05:08', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '34961a0e-0097-4609-bbce-63d16c83bdea' User entered 'None (0)'	System	12 Sep 2020 00:05:21
	System	12 Sep 2020 00:05:21

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:05:11', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '34961a0e-0097-4609-bbce-63d16c83bdea' User entered 'No (N)'	System	12 Sep 2020 00:05:21
	System	12 Sep 2020 00:05:21

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-11T20:05:18', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '34961a0e-0097-4609-bbce-63d16c83bdea' User entered '11 Sep 2020 20:05'	System	12 Sep 2020 00:05:21
	System	12 Sep 2020 00:05:21

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 5'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:53', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '468a2e97-0c71-44b6-8106-398c6e69fd9b' User entered 'None (0)'	System	13 Sep 2020 00:38:19
	System	13 Sep 2020 00:38:19

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:55', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '468a2e97-0c71-44b6-8106-398c6e69fd9b' User entered 'None (0)'	System	13 Sep 2020 00:38:19
	System	13 Sep 2020 00:38:19

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:57', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '468a2e97-0c71-44b6-8106-398c6e69fd9b' User entered 'None (0)'	System	13 Sep 2020 00:38:19
	System	13 Sep 2020 00:38:19

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:37:59', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '468a2e97-0c71-44b6-8106-398c6e69fd9b' User entered 'None (0)'	System	13 Sep 2020 00:38:19
	System	13 Sep 2020 00:38:19

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:38:01', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '468a2e97-0c71-44b6-8106-398c6e69fd9b' User entered 'None (0)'	System	13 Sep 2020 00:38:19
	System	13 Sep 2020 00:38:19

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:38:03', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '468a2e97-0c71-44b6-8106-398c6e69fd9b' User entered 'None (0)'	System	13 Sep 2020 00:38:19
	System	13 Sep 2020 00:38:19

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:38:06', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '468a2e97-0c71-44b6-8106-398c6e69fd9b' User entered 'No (N)'	System	13 Sep 2020 00:38:19
	System	13 Sep 2020 00:38:19

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-12T20:38:16', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '468a2e97-0c71-44b6-8106-398c6e69fd9b' User entered '12 Sep 2020 20:38'	System	13 Sep 2020 00:38:19
	System	13 Sep 2020 00:38:19

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 6'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:47:04', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c92b7fd3-dfd5-4bfd-bd2e-c2d660591946' User entered 'None (0)'	System	13 Sep 2020 23:47:36
	System	13 Sep 2020 23:47:36

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:47:06', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c92b7fd3-dfd5-4bfd-bd2e-c2d660591946' User entered 'None (0)'	System	13 Sep 2020 23:47:36
	System	13 Sep 2020 23:47:36

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:47:08', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c92b7fd3-dfd5-4bfd-bd2e-c2d660591946' User entered 'None (0)'	System	13 Sep 2020 23:47:36
	System	13 Sep 2020 23:47:36

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:47:10', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c92b7fd3-dfd5-4bfd-bd2e-c2d660591946' User entered 'None (0)'	System	13 Sep 2020 23:47:36
	System	13 Sep 2020 23:47:36

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:47:15', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c92b7fd3-dfd5-4bfd-bd2e-c2d660591946' User entered 'None (0)'	System	13 Sep 2020 23:47:36
	System	13 Sep 2020 23:47:36

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:47:17', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c92b7fd3-dfd5-4bfd-bd2e-c2d660591946' User entered 'None (0)'	System	13 Sep 2020 23:47:36
	System	13 Sep 2020 23:47:36

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:47:22', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c92b7fd3-dfd5-4bfd-bd2e-c2d660591946' User entered 'No (N)'	System	13 Sep 2020 23:47:36
	System	13 Sep 2020 23:47:36

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-13T19:47:32', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c92b7fd3-dfd5-4bfd-bd2e-c2d660591946'	System	13 Sep 2020 23:47:36
User entered '13 Sep 2020 19:47'	System	13 Sep 2020 23:47:36

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 7'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:05:07', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f99490d0-5209-4b48-878e-219cfa1d6210' User entered 'None (0)'	System	15 Sep 2020 00:06:22
	System	15 Sep 2020 00:06:22

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:05:10', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f99490d0-5209-4b48-878e-219cfa1d6210' User entered 'None (0)'	System	15 Sep 2020 00:06:22
	System	15 Sep 2020 00:06:22

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:05:13', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f99490d0-5209-4b48-878e-219cfa1d6210' User entered 'None (0)'	System	15 Sep 2020 00:06:22
	System	15 Sep 2020 00:06:22

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:05:15', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f99490d0-5209-4b48-878e-219cfa1d6210' User entered 'None (0)'	System	15 Sep 2020 00:06:22
	System	15 Sep 2020 00:06:22

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:05:17', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f99490d0-5209-4b48-878e-219cfa1d6210' User entered 'None (0)'	System	15 Sep 2020 00:06:22
	System	15 Sep 2020 00:06:22

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:05:19', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f99490d0-5209-4b48-878e-219cfa1d6210' User entered 'None (0)'	System	15 Sep 2020 00:06:22
	System	15 Sep 2020 00:06:22

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:05:22', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f99490d0-5209-4b48-878e-219cfa1d6210' User entered 'No (N)'	System	15 Sep 2020 00:06:22
	System	15 Sep 2020 00:06:22

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-09-14T20:06:17', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f99490d0-5209-4b48-878e-219cfa1d6210' User entered '14 Sep 2020 20:06'	System	15 Sep 2020 00:06:22
	System	15 Sep 2020 00:06:22

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:59:51

US3952052

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:02:46

US3952052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered '18 Sep 2020'	Nick Bart	25 Sep 2020 13:02:46

US3952052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Contact Made (CONTACT MADE)'	Nick Bart	25 Sep 2020 13:02:46

US3952052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered empty.	Nick Bart	25 Sep 2020 13:02:46

US3952052

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Yes (Y)'	Nick Bart	25 Sep 2020 13:02:32

US3952052

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'I'	System	25 Sep 2020 13:02:32

US3952052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	28 Sep 2020 15:15:48

US3952052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered '25 Sep 2020'	(b) (4) Nick Bart (b) (4)	28 Sep 2020 15:15:48

US3952052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4)	28 Sep 2020 15:15:48

US3952052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered empty.	Nick Bart	28 Sep 2020 15:15:48

US3952052

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	28 Sep 2020 15:15:27

US3952052

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:11:18
User entered 'I'	System	28 Sep 2020 15:15:27

US3952052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:23:45
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Yes (Y)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	29 Sep 2020 21:41:39

US3952052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:23:45
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered '29 Sep 2020'	(b) (4) Stephanie Melton (b) (4) (b) (4)	29 Sep 2020 21:41:39

US3952052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:23:45
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	29 Sep 2020 21:41:39

US3952052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:23:45
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered empty.	Stephanie Melton (b) (4)	29 Sep 2020 21:41:39

US3952052

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:23:45
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Yes (Y)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	29 Sep 2020 21:41:43

US3952052

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:23:45
User entered 'I'	System	29 Sep 2020 21:41:43

US3952052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:09:50

US3952052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '13 Oct 2020'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:09:50

US3952052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:09:50

US3952052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'VISIT2'	System	15 Oct 2020 20:09:50

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '13 Oct 2020'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '13:49'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered '13 Oct 2020 13:49'	System	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '37.0' C	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '92'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'bpm'	System	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User closed query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4)	05 Jan 2021 09:11:48
Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 17:45:30
User opened query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 14:03:19
User entered '20'	Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'breaths/min'	System	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '129'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'mmHg'	System	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '73'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:27:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'mmHg'	System	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '13 Oct 2020'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '15:49'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered '13 Oct 2020 15:49'	System	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '37.0' C	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '89'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'bpm'	System	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User closed query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4)	05 Jan 2021 09:11:54
Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 17:45:09
User opened query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 14:03:31
User entered '18'	Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'breaths/min'	System	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '128'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'mmHg'	System	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '74'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:27:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'mmHg'	System	15 Oct 2020 20:11:23

US3952052

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:27:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:10:11

US3952052

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:27:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:10:11

US3952052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4)	13 Oct 2020 19:44:16
	chrishea Harvey (b) (4)	

US3952052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4)	13 Oct 2020 19:44:16
	chrishea Harvey (b) (4)	

US3952052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4)	13 Oct 2020 19:44:16
	chrishea Harvey (b) (4)	

US3952052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 19:44:16

US3952052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '13 Oct 2020'	(b) (4)	13 Oct 2020 19:44:16
	chrishea Harvey (b) (4)	

US3952052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '15:06'	(b) (4)	13 Oct 2020 19:44:16
	chrishea Harvey (b) (4)	

US3952052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered '13 Oct 2020 15:06'	System	13 Oct 2020 19:44:16

US3952052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) chrishea Harvey (b) (4)	13 Oct 2020 19:44:16

US3952052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'ONCE'	System	13 Oct 2020 19:44:16

US3952052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:27:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 19:44:16

US3952052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:47

US3952052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '13 Oct 2020'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:47

US3952052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '14:05'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:11:47

US3952052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered '13 Oct 2020 14:05'	System	15 Oct 2020 20:11:47

US3952052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:27:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '13 Oct 2020'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:12:01

US3952052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:27:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4)	15 Oct 2020 20:12:01

US3952052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:27:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:12:01

US3952052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '14:00'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:12:01

US3952052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered '13 Oct 2020 14:00'	System	15 Oct 2020 20:12:01

US3952052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:27:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4)	15 Oct 2020 20:12:01

US3952052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:27:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:12:01

US3952052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:27:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:12:01

US3952052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered empty.	System	15 Oct 2020 20:12:01

US3952052

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	15 Oct 2020 20:10:01

US3952052

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'I'	System	15 Oct 2020 20:10:01

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:49:36', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b370d1a8-ae00-4e41-8172-5834c84765e0' User entered 'Yes (Y)'	System	13 Oct 2020 19:50:03
	System	13 Oct 2020 19:50:03

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:49:48', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b370d1a8-ae00-4e41-8172-5834c84765e0' User entered '98.6'	System	13 Oct 2020 19:50:03
	System	13 Oct 2020 19:50:03

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:49:53', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b370d1a8-ae00-4e41-8172-5834c84765e0' User entered 'No (N)'	System	13 Oct 2020 19:50:03
	System	13 Oct 2020 19:50:03

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:49:58', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b370d1a8-ae00-4e41-8172-5834c84765e0' User entered '13 Oct 2020 15:49'	System	13 Oct 2020 19:50:03
	System	13 Oct 2020 19:50:03

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Oct 2020 15:26'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Oct 2020 17:56'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:02:16', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'eaf6a7d8-1f7d-4062-aba2-32790112d33e' User entered 'Yes (Y)'	System	14 Oct 2020 00:02:41
	System	14 Oct 2020 00:02:41

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:02:31', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'eaf6a7d8-1f7d-4062-aba2-32790112d33e' User entered '96.3'	System	14 Oct 2020 00:02:41
	System	14 Oct 2020 00:02:41

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:02:35', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'eaf6a7d8-1f7d-4062-aba2-32790112d33e' User entered 'No (N)'	System	14 Oct 2020 00:02:41
	System	14 Oct 2020 00:02:41

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:02:39', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'eaf6a7d8-1f7d-4062-aba2-32790112d33e' User entered '13 Oct 2020 20:02'	System	14 Oct 2020 00:02:41
	System	14 Oct 2020 00:02:41

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Oct 2020 18:51'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 2'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:22:54', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '523d6502-2bcc-4947-8178-3cb6223bd08d' User entered 'Yes (Y)'	System	14 Oct 2020 23:23:35
	System	14 Oct 2020 23:23:35

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:23:09', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '523d6502-2bcc-4947-8178-3cb6223bd08d' User entered '98.5'	System	14 Oct 2020 23:23:35
	System	14 Oct 2020 23:23:35

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:23:25', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '523d6502-2bcc-4947-8178-3cb6223bd08d' User entered 'No (N)'	System	14 Oct 2020 23:23:35
	System	14 Oct 2020 23:23:35

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:23:31', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '523d6502-2bcc-4947-8178-3cb6223bd08d' User entered '14 Oct 2020 19:23'	System	14 Oct 2020 23:23:35
	System	14 Oct 2020 23:23:35

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 3'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:41:39', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd98622f9-1205-45ca-96f8-093ee419e81b' User entered 'Yes (Y)'	System	16 Oct 2020 10:41:59
	System	16 Oct 2020 10:41:59

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:41:49', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd98622f9-1205-45ca-96f8-093ee419e81b' User entered '97.6'	System	16 Oct 2020 10:41:59
	System	16 Oct 2020 10:41:59

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:41:52', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd98622f9-1205-45ca-96f8-093ee419e81b' User entered 'No (N)'	System	16 Oct 2020 10:41:59
	System	16 Oct 2020 10:41:59

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:41:57', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd98622f9-1205-45ca-96f8-093ee419e81b' User entered '16 Oct 2020 06:41'	System	16 Oct 2020 10:41:59
	System	16 Oct 2020 10:41:59

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 4'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:44:09', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c6e6a9a6-6751-4525-8f25-ee32e28f8420' User entered 'Yes (Y)'	System	16 Oct 2020 20:45:38
	System	16 Oct 2020 20:45:38

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:45:28', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c6e6a9a6-6751-4525-8f25-ee32e28f8420' User entered '97.0'	System	16 Oct 2020 20:45:38
	System	16 Oct 2020 20:45:38

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:45:31', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c6e6a9a6-6751-4525-8f25-ee32e28f8420'	System	16 Oct 2020 20:45:38
User entered 'No (N)'	System	16 Oct 2020 20:45:38

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:45:35', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'c6e6a9a6-6751-4525-8f25-ee32e28f8420' User entered '16 Oct 2020 16:45'	System	16 Oct 2020 20:45:38
	System	16 Oct 2020 20:45:38

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 5'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:01:07', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'bbe5ceaf-b5eb-46ff-90d7-eb73096864b9' User entered 'Yes (Y)'	System	17 Oct 2020 16:02:44
	System	17 Oct 2020 16:02:44

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:02:29', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'bbe5ceaf-b5eb-46ff-90d7-eb73096864b9' User entered '97.5'	System	17 Oct 2020 16:02:44
	System	17 Oct 2020 16:02:44

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:02:32', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'bbe5ceaf-b5eb-46ff-90d7-eb73096864b9'	System	17 Oct 2020 16:02:44
User entered 'No (N)'	System	17 Oct 2020 16:02:44

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:02:36', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'bbe5ceaf-b5eb-46ff-90d7-eb73096864b9' User entered '17 Oct 2020 12:02'	System	17 Oct 2020 16:02:44
	System	17 Oct 2020 16:02:44

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 6'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:21:48', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ee9831c2-8d0b-43a0-bf9b-67ebc5896af9' User entered 'Yes (Y)'	System	18 Oct 2020 23:23:51
	System	18 Oct 2020 23:23:51

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:23:32', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ee9831c2-8d0b-43a0-bf9b-67ebc5896af9' User entered '97.2'	System	18 Oct 2020 23:23:51
	System	18 Oct 2020 23:23:51

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:23:35', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ee9831c2-8d0b-43a0-bf9b-67ebc5896af9'	System	18 Oct 2020 23:23:51
User entered 'No (N)'	System	18 Oct 2020 23:23:51

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:23:49', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ee9831c2-8d0b-43a0-bf9b-67ebc5896af9' User entered '18 Oct 2020 19:23'	System	18 Oct 2020 23:23:51
	System	18 Oct 2020 23:23:51

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 7'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:35:58', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3a7e2d49-f53a-4a7f-a12d-5d934e9fe8e8' User entered 'Yes (Y)'	System	19 Oct 2020 21:36:12
	System	19 Oct 2020 21:36:12

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:04', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3a7e2d49-f53a-4a7f-a12d-5d934e9fe8e8' User entered '97.7'	System	19 Oct 2020 21:36:12
	System	19 Oct 2020 21:36:12

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:06', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3a7e2d49-f53a-4a7f-a12d-5d934e9fe8e8'	System	19 Oct 2020 21:36:12
User entered 'No (N)'	System	19 Oct 2020 21:36:12

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:09', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3a7e2d49-f53a-4a7f-a12d-5d934e9fe8e8'	System	19 Oct 2020 21:36:12
User entered '19 Oct 2020 17:36'	System	19 Oct 2020 21:36:12

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:50:56', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'cd91dfba-e1e7-4eb1-a6f8-7786cdae3f42'	System	13 Oct 2020 19:51:10
User entered 'None (1)'	System	13 Oct 2020 19:51:10

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:50:59', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'cd91dfba-e1e7-4eb1-a6f8-7786cdae3f42'	System	13 Oct 2020 19:51:10
User entered 'No (N)'	System	13 Oct 2020 19:51:10

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:51:01', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'cd91dfba-e1e7-4eb1-a6f8-7786cdac3f42'	System	13 Oct 2020 19:51:10
User entered 'No (N)'	System	13 Oct 2020 19:51:10

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:51:05', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'cd91dfba-e1e7-4eb1-a6f8-7786cdae3f42'	System	13 Oct 2020 19:51:10
User entered 'None (1)'	System	13 Oct 2020 19:51:10

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:51:08', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'cd91dfba-e1e7-4eb1-a6f8-7786cdac3f42'	System	13 Oct 2020 19:51:10
User entered '13 Oct 2020 15:51'	System	13 Oct 2020 19:51:10

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Oct 2020 15:26'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Oct 2020 17:56'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:02:45', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '9c85a8ae-636d-4456-b71d-3cea88805111' User entered 'None (1)'	System	14 Oct 2020 00:03:01
	System	14 Oct 2020 00:03:01

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:02:48', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '9c85a8ae-636d-4456-b71d-3cea88805111' User entered 'No (N)'	System	14 Oct 2020 00:03:01
	System	14 Oct 2020 00:03:01

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:02:50', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '9c85a8ae-636d-4456-b71d-3cea88805111' User entered 'No (N)'	System	14 Oct 2020 00:03:01
	System	14 Oct 2020 00:03:01

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:02:54', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '9c85a8ae-636d-4456-b71d-3cea88805111' User entered 'None (1)'	System	14 Oct 2020 00:03:01
	System	14 Oct 2020 00:03:01

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:02:59', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '9c85a8ae-636d-4456-b71d-3cea88805111' User entered '13 Oct 2020 20:02'	System	14 Oct 2020 00:03:01
	System	14 Oct 2020 00:03:01

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Oct 2020 18:51'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 2'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:23:38', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '309abd55-8e83-4a47-b4c0-3999cd559378'	System	14 Oct 2020 23:23:55
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 23:23:55

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:23:41', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '309abd55-8e83-4a47-b4c0-3999cd559378' User entered 'No (N)'	System	14 Oct 2020 23:23:55
	System	14 Oct 2020 23:23:55

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:23:44', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '309abd55-8e83-4a47-b4c0-3999cd559378' User entered 'No (N)'	System	14 Oct 2020 23:23:55
	System	14 Oct 2020 23:23:55

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:23:47', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '309abd55-8e83-4a47-b4c0-3999cd559378'	System	14 Oct 2020 23:23:55
User entered 'None (1)'	System	14 Oct 2020 23:23:55

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:23:52', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '309abd55-8e83-4a47-b4c0-3999cd559378' User entered '14 Oct 2020 19:23'	System	14 Oct 2020 23:23:55
	System	14 Oct 2020 23:23:55

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 3'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:42:02', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ce1bfd2b-4e65-41a9-8933-1dc7bdb9aa11' User entered 'None (1)'	System	16 Oct 2020 10:42:21
	System	16 Oct 2020 10:42:21

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:42:07', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ce1bfd2b-4e65-41a9-8933-1dc7bdb9aa11' User entered 'No (N)'	System	16 Oct 2020 10:42:21
	System	16 Oct 2020 10:42:21

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:42:10', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ce1bfd2b-4e65-41a9-8933-1dc7bdb9aa11' User entered 'No (N)'	System	16 Oct 2020 10:42:21
	System	16 Oct 2020 10:42:21

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:42:14', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ce1bfd2b-4e65-41a9-8933-1dc7bdb9aa11' User entered 'None (1)'	System	16 Oct 2020 10:42:21
	System	16 Oct 2020 10:42:21

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:42:18', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'ce1bfd2b-4e65-41a9-8933-1dc7bdb9aa11' User entered '16 Oct 2020 06:42'	System	16 Oct 2020 10:42:21
	System	16 Oct 2020 10:42:21

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 4'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:45:40', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '97f0bf23-41ed-4546-92b3-be1514e9d2ae' User entered 'None (1)'	System	16 Oct 2020 20:45:59
	System	16 Oct 2020 20:45:59

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:45:42', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '97f0bf23-41ed-4546-92b3-be1514e9d2ae' User entered 'No (N)'	System	16 Oct 2020 20:45:59
	System	16 Oct 2020 20:45:59

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:45:45', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '97f0bf23-41ed-4546-92b3-be1514e9d2ae' User entered 'No (N)'	System	16 Oct 2020 20:45:59
	System	16 Oct 2020 20:45:59

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:45:47', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '97f0bf23-41ed-4546-92b3-be1514e9d2ae' User entered 'None (1)'	System	16 Oct 2020 20:45:59
	System	16 Oct 2020 20:45:59

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:45:57', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '97f0bf23-41ed-4546-92b3-be1514e9d2ae' User entered '16 Oct 2020 16:45'	System	16 Oct 2020 20:45:59
	System	16 Oct 2020 20:45:59

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 5'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:02:41', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e716a99e-d875-4fd3-800c-5a41d9d3ac99'	System	17 Oct 2020 16:02:56
User entered 'None (1)'	System	17 Oct 2020 16:02:56

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:02:44', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e716a99e-d875-4fd3-800c-5a41d9d3ac99'	System	17 Oct 2020 16:02:56
User entered 'No (N)'	System	17 Oct 2020 16:02:56

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:02:46', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e716a99e-d875-4fd3-800c-5a41d9d3ac99'	System	17 Oct 2020 16:02:56
User entered 'No (N)'	System	17 Oct 2020 16:02:56

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:02:48', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e716a99e-d875-4fd3-800c-5a41d9d3ac99'	System	17 Oct 2020 16:02:56
User entered 'None (1)'	System	17 Oct 2020 16:02:56

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:02:53', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e716a99e-d875-4fd3-800c-5a41d9d3ac99'	System	17 Oct 2020 16:02:56
User entered '17 Oct 2020 12:02'	System	17 Oct 2020 16:02:56

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 6'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:23:53', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd9aee421-74ca-4161-b3f5-32e5087e11a3' User entered 'None (1)'	System	18 Oct 2020 23:24:09
	System	18 Oct 2020 23:24:09

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:23:55', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd9aee421-74ca-4161-b3f5-32e5087e11a3' User entered 'No (N)'	System	18 Oct 2020 23:24:09
	System	18 Oct 2020 23:24:09

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:23:58', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd9aee421-74ca-4161-b3f5-32e5087e11a3' User entered 'No (N)'	System	18 Oct 2020 23:24:09
	System	18 Oct 2020 23:24:09

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:24:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd9aee421-74ca-4161-b3f5-32e5087e11a3'	System	18 Oct 2020 23:24:09
User entered 'None (1)'	System	18 Oct 2020 23:24:09

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:24:04', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd9aee421-74ca-4161-b3f5-32e5087e11a3' User entered '18 Oct 2020 19:24'	System	18 Oct 2020 23:24:09
	System	18 Oct 2020 23:24:09

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 7'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:16', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '8c3111dc-83e8-4a1a-b6a8-549f9603c42d' User entered 'None (1)'	System	19 Oct 2020 21:36:38
	System	19 Oct 2020 21:36:38

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:22', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '8c3111dc-83e8-4a1a-b6a8-549f9603c42d' User entered 'No (N)'	System	19 Oct 2020 21:36:38
	System	19 Oct 2020 21:36:38

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:24', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '8c3111dc-83e8-4a1a-b6a8-549f9603c42d' User entered 'No (N)'	System	19 Oct 2020 21:36:38
	System	19 Oct 2020 21:36:38

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:27', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '8c3111dc-83e8-4a1a-b6a8-549f9603c42d' User entered 'None (1)'	System	19 Oct 2020 21:36:38
	System	19 Oct 2020 21:36:38

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:37', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '8c3111dc-83e8-4a1a-b6a8-549f9603c42d' User entered '19 Oct 2020 17:36'	System	19 Oct 2020 21:36:38
	System	19 Oct 2020 21:36:38

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:51:17', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd74b327d-740c-4592-8cc3-f18760bd3723' User entered 'None (0)'	System	13 Oct 2020 19:51:50
	System	13 Oct 2020 19:51:50

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:51:19', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd74b327d-740c-4592-8cc3-f18760bd3723' User entered 'None (0)'	System	13 Oct 2020 19:51:50
	System	13 Oct 2020 19:51:50

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:51:24', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd74b327d-740c-4592-8cc3-f18760bd3723' User entered 'None (0)'	System	13 Oct 2020 19:51:50
	System	13 Oct 2020 19:51:50

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:51:27', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd74b327d-740c-4592-8cc3-f18760bd3723' User entered 'None (0)'	System	13 Oct 2020 19:51:50
	System	13 Oct 2020 19:51:50

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:51:30', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd74b327d-740c-4592-8cc3-f18760bd3723' User entered 'None (0)'	System	13 Oct 2020 19:51:50
	System	13 Oct 2020 19:51:50

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:51:33', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd74b327d-740c-4592-8cc3-f18760bd3723' User entered 'None (0)'	System	13 Oct 2020 19:51:50
	System	13 Oct 2020 19:51:50

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:51:39', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd74b327d-740c-4592-8cc3-f18760bd3723' User entered 'No (N)'	System	13 Oct 2020 19:51:50
	System	13 Oct 2020 19:51:50

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T15:51:46', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'd74b327d-740c-4592-8cc3-f18760bd3723' User entered '13 Oct 2020 15:51'	System	13 Oct 2020 19:51:50
	System	13 Oct 2020 19:51:50

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Oct 2020 15:26'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Oct 2020 17:56'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:03:04', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '647d8d55-08ea-4b6e-b6f9-099359caa4ef' User entered 'None (0)'	System	14 Oct 2020 00:03:29
	System	14 Oct 2020 00:03:29

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:03:07', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '647d8d55-08ea-4b6e-b6f9-099359caa4ef' User entered 'None (0)'	System	14 Oct 2020 00:03:29
	System	14 Oct 2020 00:03:29

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:03:09', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '647d8d55-08ea-4b6e-b6f9-099359caa4ef' User entered 'None (0)'	System	14 Oct 2020 00:03:29
	System	14 Oct 2020 00:03:29

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:03:11', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '647d8d55-08ea-4b6e-b6f9-099359caa4ef' User entered 'None (0)'	System	14 Oct 2020 00:03:29
	System	14 Oct 2020 00:03:29

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:03:13', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '647d8d55-08ea-4b6e-b6f9-099359caa4ef' User entered 'None (0)'	System	14 Oct 2020 00:03:29
	System	14 Oct 2020 00:03:29

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:03:15', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '647d8d55-08ea-4b6e-b6f9-099359caa4ef' User entered 'None (0)'	System	14 Oct 2020 00:03:29
	System	14 Oct 2020 00:03:29

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:03:21', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '647d8d55-08ea-4b6e-b6f9-099359caa4ef' User entered 'No (N)'	System	14 Oct 2020 00:03:29
	System	14 Oct 2020 00:03:29

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-13T20:03:28', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '647d8d55-08ea-4b6e-b6f9-099359caa4ef' User entered '13 Oct 2020 20:03'	System	14 Oct 2020 00:03:29
	System	14 Oct 2020 00:03:29

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '13 Oct 2020 18:51'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 2'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:23:57', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '5db32a41-f640-4c42-8532-1ccbd32c7b9e'	System	14 Oct 2020 23:24:39
User entered 'No interference with activity (1)'	System	14 Oct 2020 23:24:39

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:24:02', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '5db32a41-f640-4c42-8532-1ccbd32c7b9e'	System	14 Oct 2020 23:24:39
User entered 'Some interference with activity (2)'	System	14 Oct 2020 23:24:39

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:24:06', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '5db32a41-f640-4c42-8532-1ccbd32c7b9e'	System	14 Oct 2020 23:24:39
User entered 'No interference with activity (1)'	System	14 Oct 2020 23:24:39

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:24:10', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '5db32a41-f640-4c42-8532-1ccbd32c7b9e' User entered 'No interference with activity (1)'	System	14 Oct 2020 23:24:39
	System	14 Oct 2020 23:24:39

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:24:12', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '5db32a41-f640-4c42-8532-1ccbd32c7b9e' User entered 'None (0)'	System	14 Oct 2020 23:24:39
	System	14 Oct 2020 23:24:39

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:24:17', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '5db32a41-f640-4c42-8532-1ccbd32c7b9e'	System	14 Oct 2020 23:24:39
User entered 'Some interference with activity not requiring medical attention (2)'	System	14 Oct 2020 23:24:39

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:24:22', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '5db32a41-f640-4c42-8532-1ccbd32c7b9e' User entered 'No (N)'	System	14 Oct 2020 23:24:39
	System	14 Oct 2020 23:24:39

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-14T19:24:37', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '5db32a41-f640-4c42-8532-1ccbd32c7b9e' User entered '14 Oct 2020 19:24'	System	14 Oct 2020 23:24:39
	System	14 Oct 2020 23:24:39

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 3'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:41:02', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e04082f3-3b63-49c8-8ee9-3a707d138438' User entered 'None (0)'	System	16 Oct 2020 10:41:32
	System	16 Oct 2020 10:41:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:41:07', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e04082f3-3b63-49c8-8ee9-3a707d138438' User entered 'None (0)'	System	16 Oct 2020 10:41:32
	System	16 Oct 2020 10:41:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:41:11', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e04082f3-3b63-49c8-8ee9-3a707d138438' User entered 'None (0)'	System	16 Oct 2020 10:41:32
	System	16 Oct 2020 10:41:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:41:15', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e04082f3-3b63-49c8-8ee9-3a707d138438' User entered 'None (0)'	System	16 Oct 2020 10:41:32
	System	16 Oct 2020 10:41:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:41:18', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e04082f3-3b63-49c8-8ee9-3a707d138438' User entered 'None (0)'	System	16 Oct 2020 10:41:32
	System	16 Oct 2020 10:41:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:41:21', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e04082f3-3b63-49c8-8ee9-3a707d138438' User entered 'None (0)'	System	16 Oct 2020 10:41:32
	System	16 Oct 2020 10:41:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:41:24', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e04082f3-3b63-49c8-8ee9-3a707d138438' User entered 'No (N)'	System	16 Oct 2020 10:41:32
	System	16 Oct 2020 10:41:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T06:41:30', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e04082f3-3b63-49c8-8ee9-3a707d138438' User entered '16 Oct 2020 06:41'	System	16 Oct 2020 10:41:32
	System	16 Oct 2020 10:41:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 4'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:46:02', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e9d6b2b8-549f-4228-add1-d1d2ab42c9a9' User entered 'None (0)'	System	16 Oct 2020 20:46:30
	System	16 Oct 2020 20:46:30

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:46:04', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e9d6b2b8-549f-4228-add1-d1d2ab42c9a9' User entered 'None (0)'	System	16 Oct 2020 20:46:30
	System	16 Oct 2020 20:46:30

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:46:06', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e9d6b2b8-549f-4228-add1-d1d2ab42c9a9' User entered 'None (0)'	System	16 Oct 2020 20:46:30
	System	16 Oct 2020 20:46:30

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:46:08', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e9d6b2b8-549f-4228-add1-d1d2ab42c9a9' User entered 'None (0)'	System	16 Oct 2020 20:46:30
	System	16 Oct 2020 20:46:30

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:46:10', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e9d6b2b8-549f-4228-add1-d1d2ab42c9a9' User entered 'None (0)'	System	16 Oct 2020 20:46:30
	System	16 Oct 2020 20:46:30

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:46:13', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e9d6b2b8-549f-4228-add1-d1d2ab42c9a9' User entered 'None (0)'	System	16 Oct 2020 20:46:30
	System	16 Oct 2020 20:46:30

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:46:17', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e9d6b2b8-549f-4228-add1-d1d2ab42c9a9'	System	16 Oct 2020 20:46:30
User entered 'No (N)'	System	16 Oct 2020 20:46:30

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-16T16:46:27', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e9d6b2b8-549f-4228-add1-d1d2ab42c9a9'	System	16 Oct 2020 20:46:30
User entered '16 Oct 2020 16:46'	System	16 Oct 2020 20:46:30

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 5'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:02:57', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '136cae30-3d1b-4c56-afd5-e5dfb388b81c' User entered 'None (0)'	System	17 Oct 2020 16:03:21
	System	17 Oct 2020 16:03:21

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:03:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '136cae30-3d1b-4c56-afd5-e5dfb388b81c' User entered 'None (0)'	System	17 Oct 2020 16:03:21
	System	17 Oct 2020 16:03:21

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:03:02', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '136cae30-3d1b-4c56-afd5-e5dfb388b81c' User entered 'None (0)'	System	17 Oct 2020 16:03:21
	System	17 Oct 2020 16:03:21

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:03:04', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '136cae30-3d1b-4c56-afd5-e5dfb388b81c' User entered 'None (0)'	System	17 Oct 2020 16:03:21
	System	17 Oct 2020 16:03:21

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:03:06', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '136cae30-3d1b-4c56-afd5-e5dfb388b81c' User entered 'None (0)'	System	17 Oct 2020 16:03:21
	System	17 Oct 2020 16:03:21

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:03:08', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '136cae30-3d1b-4c56-afd5-e5dfb388b81c' User entered 'None (0)'	System	17 Oct 2020 16:03:21
	System	17 Oct 2020 16:03:21

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:03:12', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '136cae30-3d1b-4c56-afd5-e5dfb388b81c' User entered 'No (N)'	System	17 Oct 2020 16:03:21
	System	17 Oct 2020 16:03:21

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-17T12:03:20', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '136cae30-3d1b-4c56-afd5-e5dfb388b81c' User entered '17 Oct 2020 12:03'	System	17 Oct 2020 16:03:21
	System	17 Oct 2020 16:03:21

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 6'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:24:08', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '87ae33eb-c16e-4191-8484-505b5a45ff7b' User entered 'None (0)'	System	18 Oct 2020 23:24:32
	System	18 Oct 2020 23:24:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:24:10', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '87ae33eb-c16e-4191-8484-505b5a45ff7b' User entered 'None (0)'	System	18 Oct 2020 23:24:32
	System	18 Oct 2020 23:24:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:24:12', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '87ae33eb-c16e-4191-8484-505b5a45ff7b' User entered 'None (0)'	System	18 Oct 2020 23:24:32
	System	18 Oct 2020 23:24:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:24:14', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '87ae33eb-c16e-4191-8484-505b5a45ff7b' User entered 'None (0)'	System	18 Oct 2020 23:24:32
	System	18 Oct 2020 23:24:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:24:16', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '87ae33eb-c16e-4191-8484-505b5a45ff7b' User entered 'None (0)'	System	18 Oct 2020 23:24:32
	System	18 Oct 2020 23:24:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:24:18', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '87ae33eb-c16e-4191-8484-505b5a45ff7b' User entered 'None (0)'	System	18 Oct 2020 23:24:32
	System	18 Oct 2020 23:24:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:24:20', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '87ae33eb-c16e-4191-8484-505b5a45ff7b' User entered 'No (N)'	System	18 Oct 2020 23:24:32
	System	18 Oct 2020 23:24:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-18T19:24:29', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '87ae33eb-c16e-4191-8484-505b5a45ff7b' User entered '18 Oct 2020 19:24'	System	18 Oct 2020 23:24:32
	System	18 Oct 2020 23:24:32

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	13 Oct 2020 19:44:16
User entered 'Day 7'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:41', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '048947cb-8f8c-4435-9168-ad1c039b8860' User entered 'None (0)'	System	19 Oct 2020 21:37:09
	System	19 Oct 2020 21:37:09

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:44', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '048947cb-8f8c-4435-9168-ad1c039b8860' User entered 'None (0)'	System	19 Oct 2020 21:37:09
	System	19 Oct 2020 21:37:09

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:47', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '048947cb-8f8c-4435-9168-ad1c039b8860' User entered 'None (0)'	System	19 Oct 2020 21:37:09
	System	19 Oct 2020 21:37:09

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:49', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '048947cb-8f8c-4435-9168-ad1c039b8860' User entered 'None (0)'	System	19 Oct 2020 21:37:09
	System	19 Oct 2020 21:37:09

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:51', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '048947cb-8f8c-4435-9168-ad1c039b8860' User entered 'None (0)'	System	19 Oct 2020 21:37:09
	System	19 Oct 2020 21:37:09

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:53', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '048947cb-8f8c-4435-9168-ad1c039b8860' User entered 'None (0)'	System	19 Oct 2020 21:37:09
	System	19 Oct 2020 21:37:09

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

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 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:36:58', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '048947cb-8f8c-4435-9168-ad1c039b8860' User entered 'No (N)'	System	19 Oct 2020 21:37:09
	System	19 Oct 2020 21:37:09

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-10-19T17:37:06', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '048947cb-8f8c-4435-9168-ad1c039b8860' User entered '19 Oct 2020 17:37'	System	19 Oct 2020 21:37:09
	System	19 Oct 2020 21:37:09

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 19:44:16

US3952052

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:27:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 19:44:16

US3952052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	03 Nov 2020 17:23:50

US3952052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered '20 Oct 2020'	(b) (4) Stephanie Melton (b) (4) (b) (4)	03 Nov 2020 17:23:50

US3952052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Contact Made (CONTACT MADE)'	Stephanie Melton (b) (4)	03 Nov 2020 17:23:50

US3952052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered empty.	(b) (4) Stephanie Melton (b) (4) (b) (4)	03 Nov 2020 17:23:50

US3952052

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Yes (Y)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	03 Nov 2020 17:23:54

US3952052

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'I'	System	03 Nov 2020 17:23:54

US3952052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	03 Nov 2020 17:24:19

US3952052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered '27 Oct 2020'	Stephanie Melton (b) (4)	03 Nov 2020 17:24:19

US3952052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Contact Made (CONTACT MADE)'	Stephanie Melton (b) (4)	03 Nov 2020 17:24:19

US3952052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered empty.	(b) (4)	
	Stephanie Melton (b) (4)	03 Nov 2020 17:24:19
	(b) (4)	

US3952052

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	03 Nov 2020 17:24:23

US3952052

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'I'	System	03 Nov 2020 17:24:23

US3952052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Yes (Y)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	03 Nov 2020 17:24:45

US3952052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered '3 Nov 2020'	(b) (4) Stephanie Melton (b) (4) (b) (4)	03 Nov 2020 17:24:45

US3952052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Contact Made (CONTACT MADE)'	Stephanie Melton (b) (4)	03 Nov 2020 17:24:45

US3952052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered empty.	(b) (4)	
	Stephanie Melton (b) (4)	03 Nov 2020 17:24:45
	(b) (4)	

US3952052

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:01:24
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	03 Nov 2020 17:24:55

US3952052

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'I'	System	03 Nov 2020 17:24:55

US3952052

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:01

US3952052

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '11 Nov 2020'	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:01

US3952052

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Clinic (Clinic)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:01

US3952052

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'VISIT3'	System	18 Nov 2020 13:24:01

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'No (N)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered empty.	System	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered empty.	System	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered empty.	System	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered empty.	System	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered empty.	System	18 Nov 2020 13:24:36

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29

US3952052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29

US3952052

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:27:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'No (N)'	(b) (4)	18 Nov 2020 13:24:51
	Brianne Okunji (b) (4)	
	(b) (4)	

US3952052

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:27:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:24:51

US3952052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:25:46

US3952052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '11 Nov 2020'	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:25:46

US3952052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered '14:37'	(b) (4)	18 Nov 2020 13:25:46
	Brianne Okunji (b) (4)	
	(b) (4)	

US3952052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered '11 Nov 2020 14:37'	System	18 Nov 2020 13:25:46

US3952052

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 19:05:39
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Nov 2020 13:25:54

US3952052

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'I'	System	18 Nov 2020 13:25:54

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 64'	System	08 Sep 2020 15:59:51

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-11-08T00:01:55', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'daa7490b-b8cb-40e8-892c-e1d353d84c96' User entered 'No (N)'	System	08 Nov 2020 05:02:19
	System	08 Nov 2020 05:02:19

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-11-08T00:02:03', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'daa7490b-b8cb-40e8-892c-e1d353d84c96'	System	08 Nov 2020 05:02:19
User entered 'No (N)'	System	08 Nov 2020 05:02:19

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2020-11-08T00:02:13', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'daa7490b-b8cb-40e8-892c-e1d353d84c96' User entered '08 Nov 2020 00:02:13'	System	08 Nov 2020 05:02:19
	System	08 Nov 2020 05:02:19

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 15:59:51

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered 'Day 71'	System	08 Sep 2020 15:59:51

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-11-15T07:50:10', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '8fbcd4dd-bde5-43be-b74a-1b715fbfa44e'	System	15 Nov 2020 12:50:32
User entered 'No (N)'	System	15 Nov 2020 12:50:32

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-11-15T07:50:18', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '8fbcd4dd-bde5-43be-b74a-1b715fbfa44e'	System	15 Nov 2020 12:50:32
User entered 'No (N)'	System	15 Nov 2020 12:50:32

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-11-15T07:50:30', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '8fbcd4dd-bde5-43be-b74a-1b715fbfa44e' User entered '15 Nov 2020 07:50:30'	System	15 Nov 2020 12:50:32
	System	15 Nov 2020 12:50:32

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 15:59:51

US3952052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:11:49
Data entry locked.	System	08 Sep 2020 15:59:51
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 15:59:51

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-11-20T07:37:23', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3bf23179-c269-4c86-9598-05066946997d'	System	20 Nov 2020 12:37:33
User entered 'No (N)'	System	20 Nov 2020 12:37:33

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-11-20T07:37:27', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3bf23179-c269-4c86-9598-05066946997d'	System	20 Nov 2020 12:37:33
User entered 'No (N)'	System	20 Nov 2020 12:37:33

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-11-20T07:37:31', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3bf23179-c269-4c86-9598-05066946997d' User entered '20 Nov 2020 07:37:31'	System	20 Nov 2020 12:37:33
	System	20 Nov 2020 12:37:33

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-11-26T06:00:53', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3355e730-3f2c-4df3-b1f3-e0338613f10b' User entered 'No (N)'	System	26 Nov 2020 11:01:07

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-11-26T06:00:59', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3355e730-3f2c-4df3-b1f3-e0338613f10b' User entered 'No (N)'	System	26 Nov 2020 11:01:07

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-11-26T06:01:02', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3355e730-3f2c-4df3-b1f3-e0338613f10b' User entered '26 Nov 2020 06:01:02'	System	26 Nov 2020 11:01:07
	System	26 Nov 2020 11:01:07

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-03T07:17:52', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b785288a-56d0-4733-8646-f54f2f75a779' User entered 'No (N)'	System	03 Dec 2020 12:18:02
	System	03 Dec 2020 12:18:02

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-03T07:17:55', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b785288a-56d0-4733-8646-f54f2f75a779'	System	03 Dec 2020 12:18:02
User entered 'No (N)'	System	03 Dec 2020 12:18:02

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-03T07:17:59', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b785288a-56d0-4733-8646-f54f2f75a779' User entered '03 Dec 2020 07:17:59'	System	03 Dec 2020 12:18:02
	System	03 Dec 2020 12:18:02

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-10T07:37:05', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '675b2dfc-e7a3-41c5-9c6e-f09369a4adb2'	System	10 Dec 2020 12:37:15
User entered 'No (N)'	System	10 Dec 2020 12:37:15

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-10T07:37:09', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '675b2dfc-e7a3-41c5-9c6e-f09369a4adb2'	System	10 Dec 2020 12:37:15
User entered 'No (N)'	System	10 Dec 2020 12:37:15

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-10T07:37:13', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '675b2dfc-e7a3-41c5-9c6e-f09369a4adb2' User entered '10 Dec 2020 07:37:13'	System	10 Dec 2020 12:37:15
	System	10 Dec 2020 12:37:15

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-17T07:54:30', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '98e37e09-3172-4184-b338-33df03e4c5d5' User entered 'No (N)'	System	17 Dec 2020 12:54:40
	System	17 Dec 2020 12:54:40

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-17T07:54:34', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '98e37e09-3172-4184-b338-33df03e4c5d5'	System	17 Dec 2020 12:54:40
User entered 'No (N)'	System	17 Dec 2020 12:54:40

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-17T07:54:37', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '98e37e09-3172-4184-b338-33df03e4c5d5' User entered '17 Dec 2020 07:54:37'	System	17 Dec 2020 12:54:40
	System	17 Dec 2020 12:54:40

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-24T07:12:15', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e1b7d6ee-d4e2-4586-81aa-4aca74c4dbf2'	System	24 Dec 2020 12:12:24
User entered 'No (N)'	System	24 Dec 2020 12:12:24

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-24T07:12:17', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e1b7d6ee-d4e2-4586-81aa-4aca74c4dbf2'	System	24 Dec 2020 12:12:24
User entered 'No (N)'	System	24 Dec 2020 12:12:24

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-24T07:12:21', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'e1b7d6ee-d4e2-4586-81aa-4aca74c4dbf2' User entered '24 Dec 2020 07:12:21'	System	24 Dec 2020 12:12:24
	System	24 Dec 2020 12:12:24

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-31T07:54:59', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '0e9407ae-5674-4a2f-9057-1dbe19ef9eeb' User entered 'No (N)'	System	31 Dec 2020 12:55:07
	System	31 Dec 2020 12:55:07

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-31T07:55:01', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '0e9407ae-5674-4a2f-9057-1dbe19ef9eeb' User entered 'No (N)'	System	31 Dec 2020 12:55:07
	System	31 Dec 2020 12:55:07

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2020-12-31T07:55:05', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '0e9407ae-5674-4a2f-9057-1dbe19ef9eeb' User entered '31 Dec 2020 07:55:05'	System	31 Dec 2020 12:55:07
	System	31 Dec 2020 12:55:07

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-01-07T07:53:09', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '1bb18f08-cc4b-464a-8d82-73b5cd8e95ea' User entered 'No (N)'	System	07 Jan 2021 12:53:18
	System	07 Jan 2021 12:53:18

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-01-07T07:53:12', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '1bb18f08-cc4b-464a-8d82-73b5cd8e95ea' User entered 'No (N)'	System	07 Jan 2021 12:53:18
	System	07 Jan 2021 12:53:18

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-01-07T07:53:16', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '1bb18f08-cc4b-464a-8d82-73b5cd8e95ea' User entered '07 Jan 2021 07:53:16'	System	07 Jan 2021 12:53:18
	System	07 Jan 2021 12:53:18

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-01-16T10:10:33', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'daf32c85-55c2-4bda-8e93-cbb63183659b' User entered 'No (N)'	System	16 Jan 2021 15:10:44
	System	16 Jan 2021 15:10:44

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-01-16T10:10:38', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'daf32c85-55c2-4bda-8e93-cbb63183659b' User entered 'No (N)'	System	16 Jan 2021 15:10:44
	System	16 Jan 2021 15:10:44

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-01-16T10:10:42', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'daf32c85-55c2-4bda-8e93-cbb63183659b' User entered '16 Jan 2021 10:10:42'	System	16 Jan 2021 15:10:44
	System	16 Jan 2021 15:10:44

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-01-23T06:43:06', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '7a7dce34-44a2-4c40-b409-a16d92f75c09' User entered 'No (N)'	System	23 Jan 2021 11:43:30
	System	23 Jan 2021 11:43:30

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-01-23T06:43:16', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '7a7dce34-44a2-4c40-b409-a16d92f75c09'	System	23 Jan 2021 11:43:30
User entered 'No (N)'	System	23 Jan 2021 11:43:30

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-01-23T06:43:26', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '7a7dce34-44a2-4c40-b409-a16d92f75c09' User entered '23 Jan 2021 06:43:26'	System	23 Jan 2021 11:43:30
	System	23 Jan 2021 11:43:30

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-01-28T07:59:01', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '182b80c2-991f-40e7-bb11-7bf2a7f99bd4' User entered 'No (N)'	System	28 Jan 2021 12:59:11
	System	28 Jan 2021 12:59:11

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-01-28T07:59:04', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '182b80c2-991f-40e7-bb11-7bf2a7f99bd4' User entered 'No (N)'	System	28 Jan 2021 12:59:11

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-01-28T07:59:09', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '182b80c2-991f-40e7-bb11-7bf2a7f99bd4' User entered '28 Jan 2021 07:59:09'	System	28 Jan 2021 12:59:11
	System	28 Jan 2021 12:59:11

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-02-06T07:00:12', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f2a17171-adb9-4e2d-89ad-e7a4f4e3717c' User entered 'No (N)'	System	06 Feb 2021 12:00:22
	System	06 Feb 2021 12:00:22

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-02-06T07:00:14', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f2a17171-adb9-4e2d-89ad-e7a4f4e3717c'	System	06 Feb 2021 12:00:22
User entered 'No (N)'	System	06 Feb 2021 12:00:22

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-02-06T07:00:19', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'f2a17171-adb9-4e2d-89ad-e7a4f4e3717c' User entered '06 Feb 2021 07:00:19'	System	06 Feb 2021 12:00:22
	System	06 Feb 2021 12:00:22

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-02-18T11:06:56', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '8292b52f-a22a-4d4d-a561-9e81cac54012' User entered 'No (N)'	System	18 Feb 2021 16:07:07
	System	18 Feb 2021 16:07:07

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-02-18T11:06:59', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '8292b52f-a22a-4d4d-a561-9e81cac54012'	System	18 Feb 2021 16:07:07
User entered 'No (N)'	System	18 Feb 2021 16:07:07

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-02-18T11:07:03', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '8292b52f-a22a-4d4d-a561-9e81cac54012' User entered '18 Feb 2021 11:07:03'	System	18 Feb 2021 16:07:07
	System	18 Feb 2021 16:07:07

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-02-25T06:55:02-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '601f10db-47ba-4d52-b69f-a846f4a18d70'	System	25 Feb 2021 11:55:32
User entered 'Yes (Y)'	System	25 Feb 2021 11:55:32

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-02-25T06:55:06-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '601f10db-47ba-4d52-b69f-a846f4a18d70'	System	25 Feb 2021 11:55:32
User entered 'No (N)'	System	25 Feb 2021 11:55:32

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-02-25T06:55:09-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '601f10db-47ba-4d52-b69f-a846f4a18d70'	System	25 Feb 2021 11:55:32
User entered 'No (N)'	System	25 Feb 2021 11:55:32

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-02-25T06:55:13-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '601f10db-47ba-4d52-b69f-a846f4a18d70'	System	25 Feb 2021 11:55:32
User entered 'Yes (Y)'	System	25 Feb 2021 11:55:32

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-02-25T06:55:18-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '601f10db-47ba-4d52-b69f-a846f4a18d70'	System	25 Feb 2021 11:55:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Feb 2021 11:55:32

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-02-25T06:55:21-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '601f10db-47ba-4d52-b69f-a846f4a18d70'	System	25 Feb 2021 11:55:32
User entered '25 Feb 2021 11:55:21'	System	25 Feb 2021 11:55:32

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-05T15:18:25-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '60bb34e9-1369-4b48-b949-5fdb2860c3f6'	System	05 Mar 2021 20:18:36
User entered 'No (N)'	System	05 Mar 2021 20:18:36

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-05T15:18:28-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '60bb34e9-1369-4b48-b949-5fdb2860c3f6'	System	05 Mar 2021 20:18:36
User entered 'No (N)'	System	05 Mar 2021 20:18:36

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-05T15:18:32-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '60bb34e9-1369-4b48-b949-5fdb2860c3f6' User entered '05 Mar 2021 15:18:32'	System	05 Mar 2021 20:18:36
	System	05 Mar 2021 20:18:36

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-11T05:35:52-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '0d4dd3d5-1f2e-46e0-bdc6-1737bf36e322'	System	11 Mar 2021 10:36:25
User entered 'Yes (Y)'	System	11 Mar 2021 10:36:25

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-11T05:35:56-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '0d4dd3d5-1f2e-46e0-bdc6-1737bf36e322'	System	11 Mar 2021 10:36:25
User entered 'No (N)'	System	11 Mar 2021 10:36:25

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-11T05:35:59-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '0d4dd3d5-1f2e-46e0-bdc6-1737bf36e322'	System	11 Mar 2021 10:36:25
User entered 'No (N)'	System	11 Mar 2021 10:36:25

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-11T05:36:08-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '0d4dd3d5-1f2e-46e0-bdc6-1737bf36e322'	System	11 Mar 2021 10:36:25
User entered 'Yes (Y)'	System	11 Mar 2021 10:36:25

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-11T05:36:11-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '0d4dd3d5-1f2e-46e0-bdc6-1737bf36e322'	System	11 Mar 2021 10:36:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Mar 2021 10:36:25

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-11T05:36:15-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '0d4dd3d5-1f2e-46e0-bdc6-1737bf36e322'	System	11 Mar 2021 10:36:25
User entered '11 Mar 2021 05:36:15'	System	11 Mar 2021 10:36:25

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-18T13:45:05-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'cb2e1223-f686-4d28-857f-fd0c4e62f39a'	System	18 Mar 2021 17:45:16
User entered 'No (N)'	System	18 Mar 2021 17:45:16

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-18T13:45:07-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'cb2e1223-f686-4d28-857f-fd0c4e62f39a'	System	18 Mar 2021 17:45:16
User entered 'No (N)'	System	18 Mar 2021 17:45:16

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-18T13:45:11-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'cb2e1223-f686-4d28-857f-fd0c4e62f39a' User entered '18 Mar 2021 13:45:11'	System	18 Mar 2021 17:45:16
	System	18 Mar 2021 17:45:16

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-25T15:44:36-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b4bc2275-e078-4717-a2ce-1ab73ebba321'	System	25 Mar 2021 19:44:47
User entered 'No (N)'	System	25 Mar 2021 19:44:47

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-25T15:44:39-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b4bc2275-e078-4717-a2ce-1ab73ebba321'	System	25 Mar 2021 19:44:47
User entered 'No (N)'	System	25 Mar 2021 19:44:47

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-25T15:44:43-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b4bc2275-e078-4717-a2ce-1ab73ebba321'	System	25 Mar 2021 19:44:47
User entered '25 Mar 2021 15:44:43'	System	25 Mar 2021 19:44:47

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-04-02T07:54:53-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '05cc963d-7800-43af-9e63-b154574614d7'	System	02 Apr 2021 11:55:02
User entered 'No (N)'	System	02 Apr 2021 11:55:02

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Have you been exposed to someone with 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 (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-04-02T07:54:55-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '05cc963d-7800-43af-9e63-b154574614d7'	System	02 Apr 2021 11:55:02
User entered 'No (N)'	System	02 Apr 2021 11:55:02

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-04-02T07:54:58-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '05cc963d-7800-43af-9e63-b154574614d7'	System	02 Apr 2021 11:55:02
User entered '02 Apr 2021 07:54:58'	System	02 Apr 2021 11:55:02

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2021-04-08T07:01:46-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'aa8d5d32-b917-4f16-ad50-847bda7734a6' User entered 'No (N)'	System	08 Apr 2021 11:01:58
	System	08 Apr 2021 11:01:58

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2021-04-08T07:01:52-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'aa8d5d32-b917-4f16-ad50-847bda7734a6' User entered 'No (N)'	System	08 Apr 2021 11:01:58

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2021-04-08T07:01:56-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'aa8d5d32-b917-4f16-ad50-847bda7734a6' User entered '08 Apr 2021 07:01:56'	System	08 Apr 2021 11:01:58
	System	08 Apr 2021 11:01:58

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2021-04-15T11:26:12-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '46df1be3-1daf-4247-88b6-3938fac630b7'	System	15 Apr 2021 15:26:23
User entered 'No (N)'	System	15 Apr 2021 15:26:23

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2021-04-15T11:26:15-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '46df1be3-1daf-4247-88b6-3938fac630b7'	System	15 Apr 2021 15:26:23
User entered 'No (N)'	System	15 Apr 2021 15:26:23

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2021-04-15T11:26:18-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '46df1be3-1daf-4247-88b6-3938fac630b7'	System	15 Apr 2021 15:26:23
User entered '15 Apr 2021 11:26:18'	System	15 Apr 2021 15:26:23

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2021-04-22T06:29:42-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3601cfc9-eb72-4b0a-8047-724de2491117'	System	22 Apr 2021 10:29:54
User entered 'No (N)'	System	22 Apr 2021 10:29:54

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

Have you been exposed to someone with 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 (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2021-04-22T06:29:46-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3601cfc9-eb72-4b0a-8047-724de2491117'	System	22 Apr 2021 10:29:54
User entered 'No (N)'	System	22 Apr 2021 10:29:54

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2021-04-22T06:29:51-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '3601cfc9-eb72-4b0a-8047-724de2491117'	System	22 Apr 2021 10:29:54
User entered '22 Apr 2021 06:29:51'	System	22 Apr 2021 10:29:54

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[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 (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2021-04-29T08:09:58-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b8869c74-e648-43d3-9069-630d8d872770'	System	29 Apr 2021 12:10:12
User entered 'No (N)'	System	29 Apr 2021 12:10:12

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Have you been exposed to someone with 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 (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2021-04-29T08:10:01-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b8869c74-e648-43d3-9069-630d8d872770'	System	29 Apr 2021 12:10:12
User entered 'No (N)'	System	29 Apr 2021 12:10:12

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (234D14F5-D544-4885-A659-D181CA8A10E0)', Time: '2021-04-29T08:10:05-04:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: 'b8869c74-e648-43d3-9069-630d8d872770'	System	29 Apr 2021 12:10:12
User entered '29 Apr 2021 08:10:05'	System	29 Apr 2021 12:10:12

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 05:58:29

US3952052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:27:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:58:29
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 05:58:29

US3952052

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:27:41

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:35:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-01T13:41:46-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '0b7b9de1-38f6-47a7-ba3c-fc7aa16d4310'	System	01 Mar 2021 18:41:57
User entered 'No (N)'	System	01 Mar 2021 18:41:57

US3952052

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:27:41

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:35:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE44717-7623-458E-A473-99F5D512BFC9)', Time: '2021-03-01T13:41:54-05:00', User OID: 'PatientReportedOutcome (US3952052)', ODM File OID: '0b7b9de1-38f6-47a7-ba3c-fc7aa16d4310' User entered '01 Mar 2021 13:41:54'	System	01 Mar 2021 18:41:57
	System	01 Mar 2021 18:41:57

US3952052

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:44:27

US3952052

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:41:29
User entered '7 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:44:27

US3952052

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:41:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:44:27

US3952052

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:44:27

US3952052

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:41:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:44:31

US3952052

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:29
User entered 'I'	System	10 Dec 2020 19:44:31

US3952052

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	20 Jan 2021 19:44:00

US3952052

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '14 Jan 2021'	(b) (4) Atanas Filev (b) (4) (b) (4)	20 Jan 2021 19:44:00

US3952052

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Atanas Filev (b) (4) (b) (4)	20 Jan 2021 19:44:00

US3952052

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Attempted Contact x3'	Atanas Filev (b) (4)	20 Jan 2021 19:44:00

US3952052

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Jan 2021 16:11:44

US3952052

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User entered 'I'	System	25 Jan 2021 16:11:44

US3952052

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:47:31

US3952052

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:47:31

US3952052

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:47:31

US3952052

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:47:31

US3952052

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:47:36

US3952052

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User entered 'I'	System	16 Mar 2021 21:47:36

US3952052

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:50:14

US3952052

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:50:14

US3952052

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:50:14

US3952052

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:27:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:50:14

US3952052

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:50:19

US3952052

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:45:44
User entered 'I'	System	16 Mar 2021 21:50:19

US3952052

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:22

US3952052

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:22

US3952052

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[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 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:22

US3952052

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User entered 'VISIT4'	System	08 Apr 2021 15:06:22

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '10:37'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User entered '07 Apr 2021 10:37'	System	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '84'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User entered 'bpm'	System	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '20'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User entered 'breaths/min'	System	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '112'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User entered 'mmHg'	System	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '62'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User entered 'mmHg'	System	08 Apr 2021 15:06:58

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56

US3952052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:27:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56

US3952052

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:27:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:07:12

US3952052

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:27:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:07:12

US3952052

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:07:37

US3952052

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:07:37

US3952052

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '10:47'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:07:37

US3952052

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User entered '07 Apr 2021 10:47'	System	08 Apr 2021 15:07:37

US3952052

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:07:46

US3952052

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:27:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:22:56
User entered 'I'	System	08 Apr 2021 15:07:46

US3952052

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

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:38:49

US3952052

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

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '24 Feb 2021'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:38:49

US3952052

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

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[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 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:38:49

US3952052

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

Form: Visit Date

Generated On: 10 Jun 2021 10:27:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User entered 'UNBLND_DECIDE'	System	24 Feb 2021 21:38:49

US3952052

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

Form: Unblinding

Generated On: 10 Jun 2021 10:27:41

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '24 Feb 2021'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:39:08

US3952052

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

Form: Unblinding

Generated On: 10 Jun 2021 10:27:41

[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 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:47:06

US3952052

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

Form: Unblinding

Generated On: 10 Jun 2021 10:27:41

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:39:08

US3952052

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

Form: Unblinding

Generated On: 10 Jun 2021 10:27:41

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:47:06

US3952052

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

Form: Unblinding

Generated On: 10 Jun 2021 10:27:41

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '24 Feb 2021'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:39:08

US3952052

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

Form: Unblinding

Generated On: 10 Jun 2021 10:27:41

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:39:08

US3952052

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

Form: Unblinding

Generated On: 10 Jun 2021 10:27:41

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:39:08

US3952052

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

Form: Unblinding

Generated On: 10 Jun 2021 10:27:41

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:39:08

US3952052

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

Form: Unblinding

Generated On: 10 Jun 2021 10:27:41

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:39:08

US3952052

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

Form: Unblinding

Generated On: 10 Jun 2021 10:27:41

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User entered empty.	System	24 Feb 2021 21:39:08

US3952052

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

Form: Unblinding

Generated On: 10 Jun 2021 10:27:41

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User entered empty.	System	24 Feb 2021 21:39:08

US3952052

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:39:18

US3952052

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '24 Feb 2021'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:39:18

US3952052

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '14:58'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:39:18

US3952052

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User entered '24 Feb 2021 14:58'	System	24 Feb 2021 21:39:18

US3952052

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:27:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:39:28

US3952052

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:27:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '24 Feb 2021'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:39:28

US3952052

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:27:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	24 Feb 2021 21:39:31
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	24 Feb 2021 21:39:31
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Feb 2021 21:39:31
User entered '15:00' reason for change: Data Entry Error	Nick Bart (b) (4)	24 Feb 2021 21:39:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Feb 2021 21:39:28
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	24 Feb 2021 21:39:28
User entered '15:0' (non-conformant).	Nick Bart (b) (4)	24 Feb 2021 21:39:28

US3952052

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:08
User entered '24 Feb 2021 15:00'	System	24 Feb 2021 21:39:31
User entered '24 Feb 2021 15:0' (non-conformant).	System	24 Feb 2021 21:39:28

US3952052

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:27:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:32:21
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:08:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:34:55
User entered 'Yes (Y)'	Nick Bart (b) (4)	24 Feb 2021 21:08:23

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:34
User entered 'USA-US215-2021-mRNA-1273-P301000005'	System	11 Mar 2021 14:18:25
User entered 'New'	(b) (4), (b) (6)	11 Mar 2021 14:18:25

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User coded data point as SOC: Infections and infestations, HLGT: Protozoal infectious disorders, HLT: Giardia infections, PT: Giardiasis, LLT: Giardiasis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 21:38:56
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 21:38:56
	(b) (4)	
Data point term sent to Coder	System	10 Mar 2021 20:09:13
Coding entries removed.	Mimi Van Der Leden	10 Mar 2021 20:08:43
	(b) (4)	
User entered 'DIARRHEA from Giardia' reason for change: New Information	Mimi Van Der Leden	10 Mar 2021 20:08:43
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diarrhoea infectious, LLT: Traveller's diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 21:21:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 21:21:01
	(b) (4)	
Data point term sent to Coder	System	24 Feb 2021 21:20:54
User entered 'traveler's diarrhea'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered 'Yes (Y)' reason for change: New Information	Mimi Van Der Leden	10 Mar 2021 20:08:43
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered '09 Feb 2021'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:20:11

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:52:29
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.	(b) (4), (b) (6)	17 Mar 2021 14:52:25
' (Site from Safety). Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.	Nick Bart (b) (4)	17 Mar 2021 13:52:40
' answered with 'updated' (Site from Safety). Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'updated' (Site from Safety).	Nick Bart (b) (4)	17 Mar 2021 13:52:36
DataPoint Un-verified.	Nick Bart (b) (4)	17 Mar 2021 13:52:18
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4)	17 Mar 2021 13:52:18
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.	(b) (4), (b) (6)	17 Mar 2021 11:26:47
' (Site from Safety). User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 11:26:13
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Mimi Van Der Leden (b) (4)	10 Mar 2021 19:34:06
User entered 'No (N)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Mar 2021 15:08:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nick Bart (b) (4) [REDACTED]	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:36:00
DataPoint Un-verified.	Nick Bart (b) (4)	17 Mar 2021 13:52:18
User entered '12 Mar 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	17 Mar 2021 13:52:18
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Mar 2021 19:34:32
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	10 Mar 2021 19:34:32
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Mar 2021 19:34:06
User entered empty; reason for change Data Entry Error	Mimi Van Der Leden (b) (4)	10 Mar 2021 19:34:06
User entered '25 Feb 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Mar 2021 15:08:35
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mimi Van Der Leden	10 Mar 2021 20:08:43
reason for change: New Information	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered 'Yes (Y)' reason for change: New Information	Mimi Van Der Leden	10 Mar 2021 20:08:43
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 16:52:16
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Waiting on hospital discharge paper ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 14:06:35
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 11:26:29
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered '1' reason for change: Data Entry Error	Mimi Van Der Leden	10 Mar 2021 20:08:43
User entered '0'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered '06 Mar 2021' reason for change: New Information	Mimi Van Der Leden	10 Mar 2021 20:08:43
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:20:11

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered '08 Mar 2021' reason for change: New Information	Mimi Van Der Leden	10 Mar 2021 20:08:43
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:20:11

US3952052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 22:13:53
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)	17 Mar 2021 11:25:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	10 Mar 2021 20:08:43
User entered 'Unknown (UNK)' reason for change:	Mimi Van Der Leden	10 Mar 2021 20:08:43
Data Entry Error	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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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)	11 Mar 2021 15:40:37
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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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)	11 Mar 2021 15:40:37
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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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)	11 Mar 2021 15:40:37
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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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)	11 Mar 2021 15:40:37
User entered 'Not Related (NOT RELATED)'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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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)	11 Mar 2021 15:40:37
User entered 'Not Related (NOT RELATED)'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered 'Not Applicable (NOT APPLICABLE)'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered 'I'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
DataPoint Un-verified.	Nick Bart (b) (4)	17 Mar 2021 13:52:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Nick Bart (b) (4)	17 Mar 2021 13:52:18
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Mimi Van Der Leden (b) (4)	10 Mar 2021 20:08:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Mimi Van Der Leden (b) (4)	10 Mar 2021 19:34:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Nick Bart (b) (4)	02 Mar 2021 15:08:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

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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)	11 Mar 2021 15:40:37
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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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 review if "blood clot on R lung" should be reported as an additional event' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 14:52:55
Query 'PV Query: please review if "blood clot on R lung" should be reported as an additional event' answered with 'See SAE#2 of Right pulmonary embolism' (Site from Safety).	Nick Bart (b) (4)	17 Mar 2021 13:51:39
User opened query 'PV Query: please review if "blood clot on R lung" should be reported as an additional event' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 11:25:37
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:00:20
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:43
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:40:37
User entered 'Subject experienced AE of 'traveler's diarrhea beginning 09Feb2021. After "30 days of diarrhea" she went to the hospital and was admitted on 06Mar2021. During hospitalization a blood clot on (R) lung was discovered per subject account.	Mimi Van Der Leden (b) (4)	10 Mar 2021 20:08:43
Found to have Giardia diarrhea and treated with metronidazole. For blood clot was given lovenox injections.		
Discharged home on 08March2021 continuing above meds. Had follow up with MD scheduled for 09Mar2021.		
Further details will be provided upon receipt of Medical Records.' reason for change: Data Entry Error		
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 20:08:43
User entered '0'	System	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 20:08:43
User entered '0'	System	24 Feb 2021 21:20:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:27:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 20:08:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered	(b) (4), (b) (6)	17 Mar 2021 14:47:16
'USA-US215-2021-mRNA-1273-P301000005'		

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 08:26:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 08:26:40
	(b) (4)	
Data point term sent to Coder	System	16 Mar 2021 16:11:32
User entered '(R) pulmonary embolism'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered 'Yes (Y)'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered 'No (N)'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered 'No (N)'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered '06 Mar 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	17 Mar 2021 13:53:20
User entered '6 Mar 2021'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered empty.	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 16:10:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered 'Yes (Y)'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 22:14:10
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:38:11
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered empty.	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered empty.	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 16:10:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered 'Yes (Y)'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered '0'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered '0'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered '1'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered '06 Mar 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	17 Mar 2021 13:53:44
User entered '6 Mar 2021'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:27:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered '08 Mar 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	17 Mar 2021 13:53:44
User entered '8 Mar 2021'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
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	16 Mar 2021 16:10:44
User entered 'Unknown (UNK)'	Mimi Van Der Leden (b) (4)	16 Mar 2021 16:10:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered empty.	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered '0'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered '0'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered '1'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered 'Not Related (NOT RELATED)'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered 'Not Related (NOT RELATED)'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered 'Not Applicable (NOT APPLICABLE)'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered '0'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered '1'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered '0'	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 22:14:19
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:37:56
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:37:51
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:37:32
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mimi Van Der Leden (b) (4)	16 Mar 2021 16:10:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered empty.	Mimi Van Der Leden	16 Mar 2021 16:10:44
	(b) (4)	

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 22:14:16
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:38:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:37:24
User entered 'During hospitalization for giardia diarrhea a (R) pulmonary embolism was discovered. Subject was started on lovenox until 13Mar2021. Began pradaxa 150 mg bid on 14Mar2021. Medical records pending.'	Mimi Van Der Leden (b) (4)	16 Mar 2021 16:10:44

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 16:10:44

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 16:10:44

US3952052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:27:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Mar 2021 16:10:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:27:41

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:32:21
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:03:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: EXENATIDE, PRODUCTSYNONYM: BYDUREON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 13:05:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 13:05:54
Data point term sent to Coder	System	25 Sep 2020 13:04:44
User entered 'Bydureon'	Nick Bart (b) (4) (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'type ii diabetes'	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered '2'	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 09:06:47
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 17:42:51
User entered 'mg (mg)' reason for change: Data Entry Error	Nick Bart (b) (4)	04 Jan 2021 17:42:47
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 15:37:53
User entered 'IU (IU)' reason for change: Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 20:12:40
User entered 'Other (OTHER)'	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User closed query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 08:39:20
Query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. Thank you.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	15 Oct 2020 20:12:43
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 20:12:40
User opened query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:05:34
User entered 'units'	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'every week (QS)'	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'un UNK 2012'	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 13:03:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	25 Sep 2020 13:03:59

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 13:05:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 13:05:54
Data point term sent to Coder	System	25 Sep 2020 13:04:44
User entered 'glipizide'	Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'type ii diabetes'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '10'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:22

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'un UNK 2018'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '0'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	24 Feb 2021 21:21:27
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Nick Bart (b) (4)	24 Feb 2021 21:21:27
User entered empty.	(b) (4)	
	Nick Bart (b) (4)	25 Sep 2020 13:04:22
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User entered '1'	System	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User entered '1'	System	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User entered '804 (804)'	System	25 Sep 2020 13:04:22

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 13:06:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 13:06:43
Data point term sent to Coder	System	25 Sep 2020 13:05:45
User entered 'metformin'	Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'type ii diabetes'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '1000'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'twice daily (BID)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'un UNK 2012'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '0'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	24 Feb 2021 21:21:54
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '19 Jan 2021' reason for change: Data Entry Error	(b) (4)	24 Feb 2021 21:21:54
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User entered '2'	System	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User entered '1'	System	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:39
User entered '804 (804)'	System	25 Sep 2020 13:04:47

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 13:06:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 13:06:42
Data point term sent to Coder	System	25 Sep 2020 13:05:47
User entered 'influenza vaccine'	Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'influenza vaccine'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '0.5'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'mL (mL)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'once (ONCE)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '24 Aug 2020'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '0'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '24 Aug 2020'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User entered empty.	System	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User entered empty.	System	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User entered empty.	System	25 Sep 2020 13:05:19

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
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)	25 Sep 2020 13:07:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 13:07:46
Data point term sent to Coder	System	25 Sep 2020 13:06:47
User entered 'pneumovax'	Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'pneumonia vaccine'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '0.5'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'mL (mL)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'once (ONCE)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '03 Feb 2020'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '0'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '03 Feb 2020'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User entered empty.	System	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User entered empty.	System	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:46
User entered empty.	System	25 Sep 2020 13:06:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 20:16:09
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 20:16:09
	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 20:14:56
User entered 'aspirin'	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'cardiac prophylaxis'	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered '81'	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'once daily (QD)'	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'un UNK 2005'	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 20:14:18

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Feb 2021 21:30:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 21:30:03
Data point term sent to Coder	System	24 Feb 2021 21:29:17
User entered 'metformin'	Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'type ii diabetes'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '2500'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '20 Jan 2021'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '0'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '09 Feb 2021'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User entered '1'	System	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User entered '1'	System	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:33
User entered '804 (804)'	System	24 Feb 2021 21:29:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 21:37:01
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	24 Feb 2021 21:37:01
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	24 Feb 2021 21:36:38
User entered 'fenofibrate'	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'hyperlipidemia'	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered '145'	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'once daily (QD)'	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'un Dec 2020'	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Feb 2021 21:35:39

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 21:37:01
	(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 Feb 2021 21:37:01
	(b) (4)	
Data point term sent to Coder	System	24 Feb 2021 21:36:37
User entered 'glipizide'	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'type ii diabetes'	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered '20'	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'twice daily (BID)'	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered '24 Feb 2021'	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Feb 2021 21:36:09

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Feb 2021 12:22:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 12:22:01
Data point term sent to Coder	System	24 Feb 2021 21:37:41
User entered 'azithromycin'	Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'traveler's diarrhea'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '250'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered empty.	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '24 Feb 2021'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '0'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	02 Mar 2021 15:09:05
User entered 'Yes (Y)'	Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered '26 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Nick Bart (b) (4)	02 Mar 2021 15:09:05
User entered empty.		
	Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User entered '1'	System	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User entered '1'	System	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:27
User entered '804 (804)'	System	24 Feb 2021 21:37:02

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 21:40:05
	(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 Feb 2021 21:40:05
	(b) (4)	
Data point term sent to Coder	System	24 Feb 2021 21:38:43
User entered 'metformin'	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'type ii diabetes'	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered '1000'	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'twice daily (BID)'	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered '09 Feb 2021'	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Feb 2021 21:38:13

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:38:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:36:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:36:53
Data point term sent to Coder	System	17 Mar 2021 13:56:16
User entered 'enoxaparin sodium injection'	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:38:36
User entered 'No (N)'	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:38:39
User entered 'right pulmonary embolism'	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:38:42
User entered '8'	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:38:43
User entered 'mL (mL)'	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:38:59
User entered empty.	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:00
User entered 'twice daily (BID)'	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:02
User entered empty.	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:04
User entered 'Subcutaneous (SUBCUTANEOUS)'	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:06
User entered empty.	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:09
User entered '06 Mar 2021'	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:11
User entered '0'	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:12
User entered 'No (N)'	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:14
User entered '13 Mar 2021'	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:16
User entered 'No (N)'	Nick Bart (b) (4)	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User entered '2'	System	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User entered '1'	System	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:23
User entered '804 (804)'	System	17 Mar 2021 13:55:21

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:07:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:07:45
Data point term sent to Coder	System	17 Mar 2021 13:56:17
User entered 'metronidazole'	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:34
User entered 'No (N)'	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:36
User entered 'diarrhea from giardia'	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:39
User entered '250'	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:42
User entered 'mg (mg)'	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:44
User entered empty.	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:48
User entered 'three times daily (TID)'	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:50
User entered empty.	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:52
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:54
User entered empty.	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:56
User entered '08 Mar 2021'	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:58
User entered '0'	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:39:59
User entered 'No (N)'	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:40:01
User entered '12 Mar 2021'	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:40:02
User entered 'No (N)'	Nick Bart (b) (4)	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User entered '3'	System	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User entered '1'	System	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:20
User entered '804 (804)'	System	17 Mar 2021 13:56:04

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT THROMBIN INHIBITORS, PRODUCT: DABIGATRAN ETEXILATE MESILATE, PRODUCTSYNONYM: PRADAXA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 13:57:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 13:57:45
	(b) (4)	
Data point term sent to Coder	System	17 Mar 2021 13:57:18
User entered 'pradaxa'	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:12
User entered 'No (N)'	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:14
User entered 'right pulmonary embolism'	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:16
User entered '150'	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:25
User entered 'mg (mg)'	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:28
User entered empty.	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:30
User entered 'twice daily (BID)'	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:32
User entered empty.	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:37
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:38
User entered empty.	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:40
User entered '14 Mar 2021'	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:41
User entered '0'	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:43
User entered 'Yes (Y)'	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:44
User entered empty.	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:40:46
User entered 'No (N)'	Nick Bart (b) (4)	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:27:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 13:56:28

US3952052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:27:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	10 Mar 2021 20:12:07

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered	System	11 Mar 2021 14:18:25
'USA-US215-2021-MRNA-1273-P301000005'		

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Yes (Y)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Yes (Y)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:35:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:53:46
Un-reviewed for Safety.	System	17 Mar 2021 14:47:16
DataPoint Un-verified.	System	17 Mar 2021 14:47:16
User entered 'Yes (Y)'	System	17 Mar 2021 14:47:16
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Mimi'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Van Der Leden'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered '15201 Shady Grove Dr'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Rockville'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered '20850'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:53:46
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:09
User entered 'US'	System	11 Mar 2021 14:19:05

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Mar 2021 14:54:05
User entered '1'	System	11 Mar 2021 14:19:05

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered	System	11 Mar 2021 14:18:25
'USA-US215-2021-MRNA-1273-P301000005'		

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Yes (Y)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Yes (Y)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:35:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:53:46
Un-reviewed for Safety.	System	17 Mar 2021 14:47:16
DataPoint Un-verified.	System	17 Mar 2021 14:47:16
User entered 'Yes (Y)'	System	17 Mar 2021 14:47:16
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Mimi'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Van Der Leden'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered '15201 Shady Grove Dr'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Rockville'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered '20850'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:53:46
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:09
User entered 'US'	System	11 Mar 2021 14:19:05

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Mar 2021 14:54:05
User entered '1'	System	11 Mar 2021 14:19:05

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:27:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:35:09
User entered '11/Mar/2021 08:19'	System	11 Mar 2021 14:19:05

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:27:41

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 19:33:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:53:46
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:09
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 14:19:05

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered	System	11 Mar 2021 14:18:25
'USA-US215-2021-MRNA-1273-P301000005'		

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Yes (Y)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Yes (Y)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:35:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:53:46
Un-reviewed for Safety.	System	17 Mar 2021 14:47:16
DataPoint Un-verified.	System	17 Mar 2021 14:47:16
User entered 'Yes (Y)'	System	17 Mar 2021 14:47:16
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'No (N)'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Mimi'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Van Der Leden'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered '15201 Shady Grove Dr'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered 'Rockville'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	11 Mar 2021 15:35:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:18:55
User entered '20850'	System	11 Mar 2021 14:18:25

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 14:53:46
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:35:09
User entered 'US'	System	11 Mar 2021 14:19:05

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:27:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Mar 2021 14:54:05
User entered '1'	System	11 Mar 2021 14:19:05

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:27:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:35:05
User entered '17/Mar/2021 10:53'	System	17 Mar 2021 14:54:05

US3952052

Folder: SAE USA-US215-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:27:41

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 19:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:35:05
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 14:54:05