

US3952116 (Prod: Synexus - Optimal Research - Rockville)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:39:34

All time stamps listed in this document are displayed in GMT

US3952116

Form: Participant Creation

Data signed: (b) (4) 08 Apr 2021 19:57:59

Generated On: 12 Aug 2021 13:39:34

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[Participant ID](#)

US3952116

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

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US3952116

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:50:14

Generated On: 12 Aug 2021 13:39:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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

US3952116

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 21:47:02

Generated On: 12 Aug 2021 13:39:34

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 21:50:14

Generated On: 12 Aug 2021 13:39:34

Date of Informed Consent ( <i>dd MMM yyyy</i> )	18 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 type="radio"/> Amendment 3 <input checked="" 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 21:50:14

Generated On: 12 Aug 2021 13:39:34

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 21:50:14

Generated On: 12 Aug 2021 13:39:34

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	DIABETES
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	GOUT [BILATERAL FEET]
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952116

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	HYPERTENSION
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)	_____

US3952116

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952116

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	OSTEOARTHRITIS OF HIP
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	OSTEOARTHRITIS OF BACK
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	CARDIAC MURMUR
Start date (dd MMM yyyy)	18 SEP 2020
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)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	DENTAL INFECTION
Start date (dd MMM yyyy)	06 AUG 2020
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)	07 SEP 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	SEP 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	NECK PAIN
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	SHOULDER PAIN
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 09 Apr 2021 20:16:05

Generated On: 12 Aug 2021 13:39:34

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1959
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 1959
Start Year (derived)	1959
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952116

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:50:14

Generated On: 12 Aug 2021 13:39:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	18 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	15:16 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 15:16
Height ( <i>xxx.x</i> )	68.5 in
Weight ( <i>xxx.x</i> )	152.0 lb
BMI ( <i>xxx.x</i> )	22.82298 kg/m <sup>2</sup>
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 21:50:14

Generated On: 12 Aug 2021 13:39:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 21:50:14

Generated On: 12 Aug 2021 13:39:34

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

WORK FROM HOME AS AN ATTORNEY. GROCERY SHOPPING TWICE WEEKLY. MEETS CLIENTS FOR WORK INFREQUENTLY.

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**Location and Living Circumstances Risk (check all that apply)**

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PRODUCTION RELEASE (v12.003  
EAB) (1725)

22 of 1988

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 21:50:14

Generated On: 12 Aug 2021 13:39:34

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	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	True
Specify	GROUP HOME WITH 3 ROOMMATES.



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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 21:52:49

Generated On: 12 Aug 2021 13:39:34

What was the date of randomization? (dd MMM yyyy) 18 SEP 2020

What was the participant's randomization number? 191127

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

Height	ND - Not Done
Weight	ND - Not Done

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

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)	18 SEP 2020
Time of assessment (00:00-23:59)	15:16 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 15:16
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

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)	18 SEP 2020
Time of assessment (00:00-23:59)	17:48 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 17:48
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:50:14

Generated On: 12 Aug 2021 13:39:34

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 18 SEP 2020

What was the treatment time? (00:00-23:59) 16:49 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 16:49

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 SEP 2020

Collection time (00:00-23:59)

16:30 (24 HR)

Collection date and time (derived)

18 SEP 2020 16:30



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 21:50:14

Generated On: 12 Aug 2021 13:39:34

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:27	18 SEP 2020 16:27
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:50:14

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 17:52

PC Open Date & Time

18 SEP 2020 17:09

PC Close Date & Time

18 SEP 2020 19:39

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 18 SEP 2020 20:34

PC Close Date & Time 19 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

19 SEP 2020 21:46

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:39:34

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**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

98.6 °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

20 SEP 2020 19:49

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

21 SEP 2020 21:50

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:39:34

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**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

22 SEP 2020 23:00

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59



US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:39:34

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**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

97.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

23 SEP 2020 21:54

---

PC Open Date & Time

23 SEP 2020 12:00

---

PC Close Date & Time

24 SEP 2020 11:59

---

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 20:39

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 17:44

PC Open Date & Time

18 SEP 2020 17:09

PC Close Date & Time

18 SEP 2020 19:39

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

18 SEP 2020 20:34

PC Close Date & Time

19 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 21:47

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 19:50

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☒

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☒

PC Time Stamp

21 SEP 2020 21:52

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 23:01

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59



US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 21:55

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 20:40

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 17:47
PC Open Date & Time	18 SEP 2020 17:09
PC Close Date & Time	18 SEP 2020 19:39

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐
- Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

- None ☐
- No interference with activity or  
1-2 episodes/24 hours ☐
- Some interference with activity  
or >2 episodes/24 hours ☐
- Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

- None ☐
- No interference with activity ☐
- Some interference with activity  
not requiring medical attention ☐
- Prevents daily activity and  
requires medical attention ☐

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 20:34

PC Close Date & Time

19 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:39:34

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 21:49
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59



US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:39:34

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 19:52
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☒

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:39:34

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 21:53
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:39:34

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 23:02
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:39:34

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 21:56
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59



US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:39:34

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 20:41
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3952116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:47:02

Generated On: 12 Aug 2021 13:39:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3952116

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:47:02

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:50:14

Generated On: 12 Aug 2021 13:39:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3952116

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:50:14

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:47:02

Generated On: 12 Aug 2021 13:39:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3952116

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:47:02

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3952116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3952116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

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)	23 OCT 2020
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 14:35
Temperature (xxx.x)	37.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3952116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

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

US3952116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3952116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

Was study treatment given? Yes ☐  
No ☒

If No, reason not given

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

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

What was the study treatment? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

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

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3952116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

15:36 (24 HR)

Collection date and time (derived)

23 OCT 2020 15:36

US3952116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

Collection date (dd MMM yyyy)			23 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:35	23 OCT 2020 15:35
Nasopharyngeal Swab 2	No		

US3952116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:52:49

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3952116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:47:02

Generated On: 12 Aug 2021 13:39:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3952116

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:47:02

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:47:02

Generated On: 12 Aug 2021 13:39:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3952116

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:47:02

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:47:02

Generated On: 12 Aug 2021 13:39:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3952116

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:47:02

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:52:53

Generated On: 12 Aug 2021 13:39:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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

US3952116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:52:53

Generated On: 12 Aug 2021 13:39:34

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) \_\_\_\_\_



US3952116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:52:53

Generated On: 12 Aug 2021 13:39:34

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3952116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:52:53

Generated On: 12 Aug 2021 13:39:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 NOV 2020

Collection time (00:00-23:59)

15:26 (24 HR)

Collection date and time (derived)

18 NOV 2020 15:26

US3952116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:52:50

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 17:55:15
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 75

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 17:27:04

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 20:59:14

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	14 DEC 2020 01:30:43
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 DEC 2020 01:19:43
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 00:36:27

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 06:01:37

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 18:07:48

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	17 JAN 2021 07:37:00
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 04:50:56

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 20:58:09

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 01:06:36

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 00:16:14

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 00:30:05

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	28 FEB 2021 05:59:43
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 173

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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07 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAR 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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14 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAR 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 187

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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21 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAR 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 APR 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 208

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 215

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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18 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 APR 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 229

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 243

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 271

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUL 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 SEP 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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10 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 OCT 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 439

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 453

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 460

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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19 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 DEC 2021 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59
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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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20 JAN 2022 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 495

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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27 JAN 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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10 FEB 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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13 FEB 2022 00:01

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17 FEB 2022 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

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20 FEB 2022 00:01

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24 FEB 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

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03 MAR 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

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06 MAR 2022 00:01

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10 MAR 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

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17 MAR 2022 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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24 MAR 2022 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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27 MAR 2022 00:01

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31 MAR 2022 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 565

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

Date and time of submission

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03 APR 2022 00:01

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07 APR 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

Date and time of submission

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10 APR 2022 00:01

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14 APR 2022 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 593

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 614

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 628

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 684

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

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04 AUG 2022 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

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07 AUG 2022 00:01

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11 AUG 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

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28 AUG 2022 00:01

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01 SEP 2022 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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08 SEP 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2022 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

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22 SEP 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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29 SEP 2022 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 747

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

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02 OCT 2022 00:01

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06 OCT 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2022 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59



US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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[Patient Cloud Open Date & Time](#)

13 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

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US3952116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

DAY 796

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59



**US3952116**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 12 Aug 2021 13:39:34**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 06:00:16

US3952116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:44:23

Generated On: 12 Aug 2021 13:39:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3952116

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:44:23

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3952116

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3952116

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3952116

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3952116**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3952116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:34

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3952116

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:34

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**US3952116**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

Was the sample collected? Yes ☐  
No ☐

Collection date (*dd MMM yyyy*) \_\_\_\_\_

Collection time (*00:00-23:59*) \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

**US3952116**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3952116**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 12 Aug 2021 13:39:34**

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"/>

**US3952116**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 12 Aug 2021 13:39:34**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3952116

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

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

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

Visit date (dd MMM yyyy)	21 JAN 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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US3952116

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Date of updated informed consent ( <i>dd MMM yyyy</i> )	21 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	21 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Height	68.5 in
Weight	157.0 lb
BMI (xxx.x)	23.57373

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Height	68.5 in
Weight	157.0 lb
BMI (xxx.x)	23.57373
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)	21 JAN 2021
Time of assessment (00:00-23:59)	15:17 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 15:17
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Height	68.5 in
Weight	157.0 lb
BMI (xxx.x)	23.57373
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)	21 JAN 2021
Time of assessment (00:00-23:59)	16:34 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 16:34
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 21 JAN 2021

What was the treatment time? (00:00-23:59) 15:54 (24 HR)

Treatment Date and Time (derived) 21 JAN 2021 15:54

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

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00-23:59)

14:32 (24 HR)

Collection date and time (derived)

21 JAN 2021 14:32



US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	21 JAN 2021
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Collection time (00:00 - 23:59)	14:34
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Collection Date and Time (derived)	21 JAN 2021 14:34
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US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952116

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3952116

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3952116

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 19:57:59

Generated On: 12 Aug 2021 13:39:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3952116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 19:57:59

Generated On: 12 Aug 2021 13:39:34

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 ( <i>dd MMM yyyy</i> )	22 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	14:32 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 14:32
Temperature ( <i>xxx.x</i> )	37.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	95 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG

US3952116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 19:57:59

Generated On: 12 Aug 2021 13:39:34

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)	22 FEB 2021
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 15:30
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3952116

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 19:57:59

Generated On: 12 Aug 2021 13:39:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 FEB 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*



US3952116

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 19:57:59

Generated On: 12 Aug 2021 13:39:34

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 FEB 2021

What was the treatment time? (00:00-23:59) 14:53 (24 HR)

Treatment Date and Time (derived) 22 FEB 2021 14:53

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3952116

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:57:59

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952116

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3952116

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952116

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3952116

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	22 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	14:14 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 14:14
Temperature ( <i>xxx.x</i> )	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	91 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952116

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3952116

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 19:57:59

Generated On: 12 Aug 2021 13:39:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 MAR 2021

Collection time (00:00-23:59)

14:22 (24 HR)

Collection date and time (derived)

22 MAR 2021 14:22



US3952116

Folder: Unscheduled 23 Oct 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Visit Date	23 OCT 2020
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Please check all assessments that apply for this visit

Physical Exam	False
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Vital Signs	True
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Immunogenicity Assessment	False
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Pregnancy Test	False
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US3952116

Folder: Unscheduled 23 Oct 2020

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 19:58:00

Generated On: 12 Aug 2021 13:39:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	23 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	15:53 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 15:53
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> )	75 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952116

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 19:11:06

Generated On: 12 Aug 2021 13:39:34

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Did the participant experience any adverse events?

Yes ☒  
No ☐

---

If Yes, enter details on the Adverse Events form.

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US3952116

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

AEID	
Adverse event	DEHYDRATION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	22 OCT 2020
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)	23 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3952116

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

AEID

Adverse event

WORSENING OF BASELINE  
ELEVATED GRADE 3 BLOOD  
PRESSURE

Was this a medically-attended AE? Yes ☐  
No ☒

Was this a Solicited Adverse Reaction? Yes ☐  
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐  
No ☒

Start date (dd MMM yyyy) 23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐  
No ☒

If not Ongoing, end date (dd MMM yyyy) 23 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐  
Grade 2/Moderate ☐  
Grade 3/Severe ☒  
Grade 4 ☐

Is the adverse event serious? Yes ☐  
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐  
No ☐  
Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

AEID	
Adverse event	XEROSIS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	16 FEB 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 19:57:59

Generated On: 12 Aug 2021 13:39:34

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

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If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication 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 (1)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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 2007	
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"/>

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication ALLOPURINAL

Prophylaxis Yes ☐  
No ☒

Indication GOUT [BILATERAL FEET]

Dose per administration 300

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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 1997
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"/>

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication COLCHICINE

Prophylaxis Yes ☐  
No ☒

Indication GOUT [BILATERAL FEET]

Dose per administration 0.6

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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 1997	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☒  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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 MAR 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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 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 (6)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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 AUG 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)	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 (7)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication SILDENAFIL

Prophylaxis Yes ☐  
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 100

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
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 (8)

Data signed: (b) (4) 09 Apr 2021 20:16:04

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Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication DENTAL INFECTION

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 SEP 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 (9)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

Dose per administration 800

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) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication ATORVASTATIN CALCIUM

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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 OCT 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 (11)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐  
No ☒

Indication DEHYDRATION

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

CONTINUOUS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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 checked="" 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)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	23 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication NECK/SHOULDER PAIN

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☒  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
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 (13)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication BANOPHEN

Prophylaxis Yes ☐  
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 25

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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)	18 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication LORATADINE

Prophylaxis Yes ☐  
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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)		18 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Name of Medication FLUOCINONIDE CREAM

Prophylaxis Yes ☐  
No ☒

Indication XEROSIS

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

366 of 1988

EAB) (1725)

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

	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)	18 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3952116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 19:57:59

Generated On: 12 Aug 2021 13:39:34

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3952116

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 09 Apr 2021 20:16:04

Generated On: 12 Aug 2021 13:39:34

Date of dosing discontinuation (dd MMM yyyy) 23 OCT 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

AE #2 [WORSENING OF  
BASELINE ELEVATED GRADE 3  
BLOOD PRESSURE]

US3952116

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:39:34

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3952116 (Prod: Synexus - Optimal Research - Rockville)

**US3952116**

**Form: Participant Creation**

**Generated On: 12 Aug 2021 13:39:34**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'US3952116'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Sep 2020 20:04:12

**US3952116**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:36:33

**US3952116**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '18 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 20:04:13

**US3952116**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:36:33



**US3952116**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'SCRN'	System	22 Sep 2020 18:36:33

US3952116

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered (b) (6) 1945'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 20:04:14

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered '75'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:36:52

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'YEARS'	System	22 Sep 2020 18:36:52

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '75'	System	18 Sep 2020 21:29:43

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Male (M)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:36:52

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:36:52

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:36:52



**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'I'	Nick Bart (b) (4)	22 Sep 2020 18:36:52

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:36:52

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:36:52

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:36:52

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:36:52

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:36:52

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:36:52

**US3952116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:39:34**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:36:52



**US3952116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:39:34**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '18 Sep 2020'	Brianne Okunji (b) (4)	18 Sep 2020 21:29:43

**US3952116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:39:34**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Sep 2020'	System	18 Sep 2020 21:29:43

**US3952116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:39:34**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2020'	System	18 Sep 2020 21:29:43

**US3952116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:39:34**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Amendment 3 (3)'	Brianne Okunji (b) (4)	18 Sep 2020 21:29:43

**US3952116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:39:34**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	Brianne Okunji (b) (4)	18 Sep 2020 21:29:43

**US3952116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:39:34**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	Brianne Okunji (b) (4)	18 Sep 2020 21:29:43

**US3952116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:39:34**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	Brianne Okunji (b) (4)	18 Sep 2020 21:29:43

**US3952116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:39:34**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	Brianne Okunji (b) (4)	18 Sep 2020 21:29:43



**US3952116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:39:34**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 20:04:13

**US3952116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:39:34**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '1'	System	18 Sep 2020 21:29:49

**US3952116**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 12 Aug 2021 13:39:34**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	Brianne Okunji (b) (4)	18 Sep 2020 21:29:49

**US3952116**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 12 Aug 2021 13:39:34**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:39:57

US3952116

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:39:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 18:40:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:40:38
Data point term sent to Coder	System	22 Sep 2020 18:40:15
User entered 'diabetes'	Nick Bart (b) (4)	22 Sep 2020 18:40:10

**US3952116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'un UNK 2007'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:10

**US3952116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:10

**US3952116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:10



**US3952116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:10

**US3952116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:10

**US3952116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Jan 2007'	System	22 Sep 2020 18:40:10

**US3952116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2007'	System	22 Sep 2020 18:40:10

**US3952116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	22 Sep 2020 18:40:10

**US3952116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	22 Sep 2020 18:40:10

US3952116

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:39:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 00:48:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 00:48:36
Data point term sent to Coder	System	04 Jan 2021 20:30:31
Coding entries removed.	Nick Bart (b) (4)	04 Jan 2021 20:30:05
User entered 'GOUT [bilateral feet]' reason for change: New Information	Nick Bart (b) (4)	04 Jan 2021 20:30:05
Query 'Per DM CLR: Please update the condition to include the location of Gout (i.e. bilateral, left, right - big toe, ankles, knees, elbows, wrists, fingers, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	04 Nov 2020 12:29:06
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please update the condition to include the location of Gout (i.e. bilateral, left, right - big toe, ankles, knees, elbows, wrists, fingers, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	29 Oct 2020 14:44:28
' (Site from DM).		
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:41:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:41:45
Data point term sent to Coder	System	22 Sep 2020 18:41:17
User entered 'gout'	Nick Bart (b) (4)	22 Sep 2020 18:40:19

**US3952116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'un UNK 1995'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:19



**US3952116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:19

**US3952116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:19

**US3952116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:19

**US3952116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:19

**US3952116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Jan 1995'	System	22 Sep 2020 18:40:19

**US3952116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '1995'	System	22 Sep 2020 18:40:19

**US3952116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	22 Sep 2020 18:40:19

**US3952116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	22 Sep 2020 18:40:19



US3952116

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:39:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 18:41:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:41:45
Data point term sent to Coder	System	22 Sep 2020 18:41:18
User entered 'hypertension'	Nick Bart (b) (4)	22 Sep 2020 18:40:29

**US3952116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'un UNK 2012'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:29

**US3952116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:29

**US3952116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:29

**US3952116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:29

**US3952116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:29

**US3952116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Jan 2012'	System	22 Sep 2020 18:40:29

**US3952116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2012'	System	22 Sep 2020 18:40:29



**US3952116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	22 Sep 2020 18:40:29

**US3952116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	22 Sep 2020 18:40:29

US3952116

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:39:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 18:41:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:41:45
Data point term sent to Coder	System	22 Sep 2020 18:41:18
User entered 'acid reflux'	Nick Bart (b) (4)	22 Sep 2020 18:40:39

**US3952116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'un UNK 2015'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:39

**US3952116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:39

**US3952116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:39

**US3952116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:39

**US3952116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:39



**US3952116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Jan 2015'	System	22 Sep 2020 18:40:39

**US3952116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2015'	System	22 Sep 2020 18:40:39

**US3952116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	22 Sep 2020 18:40:39

**US3952116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	22 Sep 2020 18:40:39

US3952116

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:39:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 18:41:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:41:46
Data point term sent to Coder	System	22 Sep 2020 18:41:18
User entered 'erectile dysfunction'	Nick Bart (b) (4)	22 Sep 2020 18:40:54

**US3952116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'un UNK 2013'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:54

**US3952116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:54

**US3952116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:54



**US3952116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:54

**US3952116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:40:54

**US3952116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Jan 2013'	System	22 Sep 2020 18:40:54

**US3952116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2013'	System	22 Sep 2020 18:40:54

**US3952116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	22 Sep 2020 18:40:54

**US3952116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	22 Sep 2020 18:40:54

US3952116

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:39:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User closed query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 08). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:38:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:22:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:22:40
Query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 08). ' answered with 'done' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 19:21:38
Data point term sent to Coder	System	10 Nov 2020 19:21:30
User entered 'OSTEOARTHRITIS OF HIp' reason for change: Per Query Resolution	Nick Bart (b) (4)	10 Nov 2020 19:21:27
User opened query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 08). ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 18:05:06
Data point term sent to Coder	System	22 Sep 2020 18:41:19
User entered 'osteoarthritis of hip and back'	Nick Bart (b) (4)	22 Sep 2020 18:41:14

**US3952116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'un UNK 2020'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:14



**US3952116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:14

**US3952116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:14

**US3952116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:14

**US3952116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:14

**US3952116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Jan 2020'	System	22 Sep 2020 18:41:14

**US3952116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2020'	System	22 Sep 2020 18:41:14

**US3952116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	22 Sep 2020 18:41:14

**US3952116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	22 Sep 2020 18:41:14



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Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:39:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	12 Oct 2020 19:05:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 19:05:25
Data point term sent to Coder	System	12 Oct 2020 19:04:16
User entered 'hyperlipidemia'	Nick Bart (b) (4)	12 Oct 2020 19:04:15

**US3952116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'un UNK 2007'	(b) (4) Nick Bart (b) (4)	12 Oct 2020 19:04:15

**US3952116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	12 Oct 2020 19:04:15

**US3952116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	12 Oct 2020 19:04:15

**US3952116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	12 Oct 2020 19:04:15

**US3952116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	12 Oct 2020 19:04:15

**US3952116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Jan 2007'	System	12 Oct 2020 19:04:15

**US3952116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2007'	System	12 Oct 2020 19:04:15



**US3952116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	12 Oct 2020 19:04:15

**US3952116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	12 Oct 2020 19:04:15

US3952116

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:39:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis spinal - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 19:23:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:23:39
Data point term sent to Coder	System	10 Nov 2020 19:22:32
User entered 'osteoarthritis of back'	Nick Bart (b) (4)	10 Nov 2020 19:21:58

**US3952116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'un UNK 2020'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:21:58

**US3952116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:21:58

**US3952116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:21:58

**US3952116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:21:58

**US3952116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:21:58



**US3952116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Jan 2020'	System	10 Nov 2020 19:21:58

**US3952116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2020'	System	10 Nov 2020 19:21:58

**US3952116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	10 Nov 2020 19:21:58

**US3952116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	10 Nov 2020 19:21:58

US3952116

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:39:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User coded data point as SOC: Investigations, HLT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Dec 2020 20:20:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 20:20:10
Data point term sent to Coder	System	10 Dec 2020 20:18:55
User entered 'cardiac murmur'	Nick Bart (b) (4)	10 Dec 2020 20:18:45

**US3952116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '18 Sep 2020'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:18:45

**US3952116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:18:45

**US3952116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:18:45



**US3952116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:18:45

**US3952116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:18:45

**US3952116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Sep 2020'	System	10 Dec 2020 20:18:45

**US3952116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2020'	System	10 Dec 2020 20:18:45

**US3952116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	10 Dec 2020 20:18:45

**US3952116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	10 Dec 2020 20:18:45

US3952116

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:39:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth infection, LLT: Tooth infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 19:37:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:37:30
Data point term sent to Coder	System	05 Jan 2021 19:36:13
User entered 'dental infection'	Nick Bart (b) (4)	05 Jan 2021 19:35:52

**US3952116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '06 Aug 2020'	(b) (4) Nick Bart (b) (4)	05 Jan 2021 19:35:52



**US3952116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Jan 2021 19:35:52

**US3952116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	05 Jan 2021 19:35:52

**US3952116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '07 Sep 2020'	(b) (4) Nick Bart (b) (4)	05 Jan 2021 19:35:52

**US3952116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	05 Jan 2021 19:35:52

**US3952116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Aug 2020'	System	05 Jan 2021 19:35:52

**US3952116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2020'	System	05 Jan 2021 19:35:52

**US3952116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Sep 2020'	System	05 Jan 2021 19:35:52

**US3952116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2020'	System	05 Jan 2021 19:35:52



US3952116

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:39:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Jan 2021 19:07:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 19:07:20
Data point term sent to Coder	System	28 Jan 2021 19:07:00
User entered 'neck pain'	Nick Bart (b) (4)	28 Jan 2021 19:06:09

**US3952116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'un UNK 2013'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:06:09

**US3952116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:06:09

**US3952116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:06:09

**US3952116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:06:09

**US3952116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:06:09

**US3952116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Jan 2013'	System	28 Jan 2021 19:06:09

**US3952116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2013'	System	28 Jan 2021 19:06:09



**US3952116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	28 Jan 2021 19:06:09

**US3952116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	28 Jan 2021 19:06:09

US3952116

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:39:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	28 Jan 2021 19:07:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 19:07:21
Data point term sent to Coder	System	28 Jan 2021 19:07:01
User entered 'shoulder pain'	Nick Bart (b) (4)	28 Jan 2021 19:06:20

**US3952116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'un UNK 2013'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:06:20

**US3952116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:06:20

**US3952116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:06:20

**US3952116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:06:20

**US3952116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:06:20



**US3952116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Jan 2013'	System	28 Jan 2021 19:06:20

**US3952116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '2013'	System	28 Jan 2021 19:06:20

**US3952116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	28 Jan 2021 19:06:20

**US3952116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	28 Jan 2021 19:06:20

US3952116

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:39:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 22:46:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 22:46:58
Data point term sent to Coder	System	08 Apr 2021 22:46:18
User entered 'Allergic Rhinitis'	(b) (4), (b) (6)	08 Apr 2021 22:45:32

**US3952116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'un UNK 1959'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:45:32

**US3952116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:45:32

**US3952116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:45:32



**US3952116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:39:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:45:32

**US3952116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:45:32

**US3952116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'Jan 1959'	System	08 Apr 2021 22:45:32

**US3952116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '1959'	System	08 Apr 2021 22:45:32

**US3952116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	08 Apr 2021 22:45:32

**US3952116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered empty.	System	08 Apr 2021 22:45:32

**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:39:42

**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '18 Sep 2020'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:39:42



**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '15:16'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:39:42

**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '18 Sep 2020 15:16'	System	22 Sep 2020 18:39:42

US3952116

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:34

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '68.5' in	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:39:42
DataPoint set to visible.	System	18 Sep 2020 21:29:49

**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '152.0' lb	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:39:42
DataPoint set to visible.	System	18 Sep 2020 21:29:49

**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered '22.82298'	System	22 Sep 2020 18:39:42
DataPoint set to visible.	System	18 Sep 2020 21:29:49

US3952116

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'kg/m2'	System	22 Sep 2020 18:39:42
DataPoint set to visible.	System	18 Sep 2020 21:29:49

US3952116

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
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)	12 Nov 2020 10:00:14
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)	10 Nov 2020 19:22:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 19:22:22
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 14:55:51
User entered '37.0' C	Nick Bart (b) (4)	22 Sep 2020 18:39:42

**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty; reason for change Data Entry Error	(b) (4)	10 Nov 2020 19:22:22
User entered 'Oral (Oral)'	Nick Bart (b) (4)	22 Sep 2020 18:39:42



**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:39:42

**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 19:22:22
User entered '67'	Nick Bart (b) (4)	22 Sep 2020 18:39:42

**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'bpm'	System	22 Sep 2020 18:39:42

US3952116

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 19:22:22
User entered '12'	Nick Bart (b) (4)	22 Sep 2020 18:39:42

US3952116

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'breaths/min'	System	22 Sep 2020 18:39:42

US3952116

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 19:22:22
User entered '131'	Nick Bart (b) (4)	22 Sep 2020 18:39:42

**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'mmHg'	System	22 Sep 2020 18:39:42

US3952116

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 19:22:22
User entered '81'	Nick Bart (b) (4)	22 Sep 2020 18:39:42



**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User entered 'mmHg'	System	22 Sep 2020 18:39:42

**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57

**US3952116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 18:32:57

**US3952116**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:39:34**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:39:04

**US3952116**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:39:34**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '18 Sep 2020'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:39:04

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:38:53



US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:38:53



**US3952116**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 12 Aug 2021 13:39:34**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'work from home as an attorney. grocery shopping twice weekly. meets clients for work infrequently.'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53



**US3952116**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 12 Aug 2021 13:39:34**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'I'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53

US3952116

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:32:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'group home with 3 roommates.'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:38:53

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:28

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '18 Sep 2020'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:28

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[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 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:28

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'VISIT1'	System	22 Sep 2020 18:41:28

US3952116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:39:34

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '18 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 20:09:23

US3952116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:39:34

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '191127'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 20:09:23



US3952116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:39:34

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 20:09:23

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:39:34**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:43:19

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:39:34**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:43:19

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:39:34**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:43:19

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:39:34**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:43:19

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:39:34**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:43:19

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:39:34**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:43:19
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:33:05
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:33:04

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
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)	12 Nov 2020 10:35:59
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)	10 Nov 2020 19:22:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 19:22:45
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 14:56:03
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43



US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 19:22:45
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
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)	12 Nov 2020 10:35:59
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)	10 Nov 2020 19:22:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 19:22:45
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 14:56:03
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 19:22:45
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
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)	
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).	(b) (4), (b) (6)	12 Nov 2020 07:41:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 19:23:54
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)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 14:56:12
	Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 19:23:49
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '15:16' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 19:23:49
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered '18 Sep 2020 15:16'	System	10 Nov 2020 19:23:49
User entered empty.	System	22 Sep 2020 18:42:43



US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '37.0' C reason for change: Data Entry Error	(b) (4)	10 Nov 2020 19:23:49
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 19:23:49
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '67' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 19:23:49
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'bpm'	System	10 Nov 2020 19:23:49
User entered empty.	System	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '12' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 19:23:49
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'breaths/min'	System	10 Nov 2020 19:23:49
User entered empty.	System	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '131' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 19:23:49
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43



US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'mmHg'	System	10 Nov 2020 19:23:49
User entered empty.	System	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '81' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 19:23:49
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'mmHg'	System	10 Nov 2020 19:23:49
User entered empty.	System	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
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)	12 Nov 2020 10:35:59
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)	10 Nov 2020 19:22:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 19:22:45
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 14:56:03
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 19:22:45
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	22 Sep 2020 18:42:43

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:43

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '18 Sep 2020'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:43



**US3952116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '17:48'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:43

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered '18 Sep 2020 17:48'	System	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '37.1' C	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:43

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:43

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '63'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:43

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'bpm'	System	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '12'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:43



US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'breaths/min'	System	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4)	05 Jan 2021 09:27:46
Query 'Per CDM: Per CCG V2.0 page 50, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 20:08:08
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 18:25:41
User entered '149'	Nick Bart (b) (4)	22 Sep 2020 18:42:43

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'mmHg'	System	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '88'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:43

US3952116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'mmHg'	System	22 Sep 2020 18:42:43

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:39:34**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:38

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:39:34**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:38

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Sep 2020 21:30:27



**US3952116**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Sep 2020 21:30:27

US3952116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	Brianne Okunji (b) (4)	18 Sep 2020 21:30:27

US3952116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 21:30:27

US3952116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '18 Sep 2020'	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Sep 2020 21:30:27

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '16:49'	Brianne Okunji (b) (4)	18 Sep 2020 21:30:27

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered '18 Sep 2020 16:49'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	18 Sep 2020 21:30:27

US3952116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'ONCE'	System	18 Sep 2020 21:30:27



US3952116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:54

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '18 Sep 2020'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:54

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '16:30'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:54

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered '18 Sep 2020 16:30'	System	22 Sep 2020 18:41:54

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 12 Aug 2021 13:39:34**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '18 Sep 2020'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:09

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4)	22 Sep 2020 18:42:09

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:09



**US3952116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:39:34**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '16:27'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:09

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered '18 Sep 2020 16:27'	System	22 Sep 2020 18:42:09

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4)	22 Sep 2020 18:42:09

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:09

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:39:34**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:42:09

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered empty.	System	22 Sep 2020 18:42:09

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:41:41

**US3952116**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered '1'	System	22 Sep 2020 18:41:41



US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:51:56', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '479efa62-2628-4a0c-b75b-dd504f0b6c78' User entered 'Yes (Y)'	System	18 Sep 2020 21:52:39
	System	18 Sep 2020 21:52:39

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:52:15', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '479efa62-2628-4a0c-b75b-dd504f0b6c78' User entered '98.8'	System	18 Sep 2020 21:52:39
	System	18 Sep 2020 21:52:39

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:52:23', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '479efa62-2628-4a0c-b75b-dd504f0b6c78' User entered 'No (N)'	System	18 Sep 2020 21:52:39
	System	18 Sep 2020 21:52:39

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:52:36', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '479efa62-2628-4a0c-b75b-dd504f0b6c78' User entered '18 Sep 2020 17:52'	System	18 Sep 2020 21:52:39
	System	18 Sep 2020 21:52:39

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '18 Sep 2020 17:09'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '18 Sep 2020 19:39'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 21:30:27



US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '18 Sep 2020 20:34'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 21:30:27



US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 2'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:39:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:43:53', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '6f810088-d82d-44ff-9b1b-d921368e3f46'	System	20 Sep 2020 01:46:22
User entered 'Yes (Y)'	System	20 Sep 2020 01:46:22

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:39:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:44:28', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '6f810088-d82d-44ff-9b1b-d921368e3f46'	System	20 Sep 2020 01:46:22
User entered '97.8'	System	20 Sep 2020 01:46:22

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:39:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:45:26', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '6f810088-d82d-44ff-9b1b-d921368e3f46'	System	20 Sep 2020 01:46:22
User entered 'Yes (Y)'	System	20 Sep 2020 01:46:22

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:39:34

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reported in dairy in error, spoke to patient and they reported no medication taken. ' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 12:17:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:45:57', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '6f810088-d82d-44ff-9b1b-d921368e3f46' User entered '1'	chrishea Harvey (b) (4)	11 Nov 2020 16:27:24
	System	20 Sep 2020 01:46:22
	System	20 Sep 2020 01:46:22
	System	20 Sep 2020 01:46:22

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:39:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:45:57', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '6f810088-d82d-44ff-9b1b-d921368e3f46'	System	20 Sep 2020 01:46:22
User entered '0'	System	20 Sep 2020 01:46:22

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:46:20', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '6f810088-d82d-44ff-9b1b-d921368e3f46'	System	20 Sep 2020 01:46:22
User entered '19 Sep 2020 21:46'	System	20 Sep 2020 01:46:22

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 21:30:27



**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 3'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:39:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:47:49', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'be6c29a0-2b96-4073-9e09-92f4d8fb2a97'	System	20 Sep 2020 23:49:08
User entered 'Yes (Y)'	System	20 Sep 2020 23:49:08

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:39:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:48:23', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'be6c29a0-2b96-4073-9e09-92f4d8fb2a97' User entered '98.6'	System	20 Sep 2020 23:49:08
	System	20 Sep 2020 23:49:08

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:39:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:48:35', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'be6c29a0-2b96-4073-9e09-92f4d8fb2a97'	System	20 Sep 2020 23:49:08
User entered 'No (N)'	System	20 Sep 2020 23:49:08

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:49:06', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'be6c29a0-2b96-4073-9e09-92f4d8fb2a97'	System	20 Sep 2020 23:49:08
User entered '20 Sep 2020 19:49'	System	20 Sep 2020 23:49:08

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:30:27



US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 4'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:39:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:49:05', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'b1ca68c2-416c-4742-897b-e302644b591a' User entered 'Yes (Y)'	System	22 Sep 2020 01:50:25
	System	22 Sep 2020 01:50:25

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:39:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:50:02', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'b1ca68c2-416c-4742-897b-e302644b591a' User entered '98.6'	System	22 Sep 2020 01:50:25
	System	22 Sep 2020 01:50:25

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:39:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:50:08', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'b1ca68c2-416c-4742-897b-e302644b591a' User entered 'No (N)'	System	22 Sep 2020 01:50:25
	System	22 Sep 2020 01:50:25

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:50:23', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'b1ca68c2-416c-4742-897b-e302644b591a' User entered '21 Sep 2020 21:50'	System	22 Sep 2020 01:50:25
	System	22 Sep 2020 01:50:25

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 5'	System	18 Sep 2020 21:30:27



US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:39:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T22:59:45', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '773cda6a-94b8-448d-9318-46b4e548d008' User entered 'Yes (Y)'	System	23 Sep 2020 03:00:27
	System	23 Sep 2020 03:00:27

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:39:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:00:06', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '773cda6a-94b8-448d-9318-46b4e548d008' User entered '97.5'	System	23 Sep 2020 03:00:27
	System	23 Sep 2020 03:00:27

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:39:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:00:12', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '773cda6a-94b8-448d-9318-46b4e548d008'	System	23 Sep 2020 03:00:27
User entered 'No (N)'	System	23 Sep 2020 03:00:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:00:25', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '773cda6a-94b8-448d-9318-46b4e548d008' User entered '22 Sep 2020 23:00'	System	23 Sep 2020 03:00:27
	System	23 Sep 2020 03:00:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 6'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:54:02', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '71249f2e-f170-43eb-951b-7e875fd3bcb9' User entered 'Yes (Y)'	System	24 Sep 2020 01:54:44
	System	24 Sep 2020 01:54:44



US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:39:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:54:25', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '71249f2e-f170-43eb-951b-7e875fd3bcb9' User entered '97.9'	System	24 Sep 2020 01:54:44
	System	24 Sep 2020 01:54:44

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:39:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:54:32', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '71249f2e-f170-43eb-951b-7e875fd3bcb9'	System	24 Sep 2020 01:54:44
User entered 'No (N)'	System	24 Sep 2020 01:54:44

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:54:41', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '71249f2e-f170-43eb-951b-7e875fd3bcb9' User entered '23 Sep 2020 21:54'	System	24 Sep 2020 01:54:44
	System	24 Sep 2020 01:54:44

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 7'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:39:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:39:21', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '0f022d88-4bad-409c-8684-41a2bd391794' User entered 'Yes (Y)'	System	25 Sep 2020 00:39:56
	System	25 Sep 2020 00:39:56

US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:39:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:39:37', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '0f022d88-4bad-409c-8684-41a2bd391794' User entered '97.1'	System	25 Sep 2020 00:39:56
	System	25 Sep 2020 00:39:56



US3952116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:39:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:39:43', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '0f022d88-4bad-409c-8684-41a2bd391794' User entered 'No (N)'	System	25 Sep 2020 00:39:56
	System	25 Sep 2020 00:39:56

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:39:51', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '0f022d88-4bad-409c-8684-41a2bd391794' User entered '24 Sep 2020 20:39'	System	25 Sep 2020 00:39:56
	System	25 Sep 2020 00:39:56

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:43:54', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '70b00f13-1025-41cb-9dcb-8e3b9aa3e015' User entered 'None (1)'	System	18 Sep 2020 21:44:35
	System	18 Sep 2020 21:44:35

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:44:03', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '70b00f13-1025-41cb-9dcb-8e3b9aa3e015' User entered 'No (N)'	System	18 Sep 2020 21:44:35
	System	18 Sep 2020 21:44:35

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:44:09', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '70b00f13-1025-41cb-9dcb-8e3b9aa3e015' User entered 'No (N)'	System	18 Sep 2020 21:44:35
	System	18 Sep 2020 21:44:35



US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:44:19', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '70b00f13-1025-41cb-9dcb-8e3b9aa3e015'	System	18 Sep 2020 21:44:35
User entered 'None (1)'	System	18 Sep 2020 21:44:35

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:44:31', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '70b00f13-1025-41cb-9dcb-8e3b9aa3e015' User entered '18 Sep 2020 17:44'	System	18 Sep 2020 21:44:35
	System	18 Sep 2020 21:44:35

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '18 Sep 2020 17:09'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '18 Sep 2020 19:39'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59



US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '18 Sep 2020 20:34'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 2'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:39:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:47:03', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'dfb44f52-5d75-4f08-b144-18e9a0b3c755'	System	20 Sep 2020 01:47:57
User entered 'None (1)'	System	20 Sep 2020 01:47:57



US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:39:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:47:09', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'dfb44f52-5d75-4f08-b144-18e9a0b3c755'	System	20 Sep 2020 01:47:57
User entered 'No (N)'	System	20 Sep 2020 01:47:57

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:39:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:47:20', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'dfb44f52-5d75-4f08-b144-18e9a0b3c755'	System	20 Sep 2020 01:47:57
User entered 'No (N)'	System	20 Sep 2020 01:47:57

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:39:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:47:30', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'dfb44f52-5d75-4f08-b144-18e9a0b3c755'	System	20 Sep 2020 01:47:57
User entered 'None (1)'	System	20 Sep 2020 01:47:57

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:47:54', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'dfb44f52-5d75-4f08-b144-18e9a0b3c755'	System	20 Sep 2020 01:47:57
User entered '19 Sep 2020 21:47'	System	20 Sep 2020 01:47:57

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 3'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:39:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:49:23', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e1e0c733-eb41-4b57-85cb-12662b89b476'	System	20 Sep 2020 23:50:24
User entered 'None (1)'	System	20 Sep 2020 23:50:24



US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:39:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:49:29', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e1e0c733-eb41-4b57-85cb-12662b89b476' User entered 'No (N)'	System	20 Sep 2020 23:50:24
	System	20 Sep 2020 23:50:24

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:39:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:49:35', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e1e0c733-eb41-4b57-85cb-12662b89b476' User entered 'No (N)'	System	20 Sep 2020 23:50:24
	System	20 Sep 2020 23:50:24

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:39:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:49:42', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e1e0c733-eb41-4b57-85cb-12662b89b476'	System	20 Sep 2020 23:50:24
User entered 'None (1)'	System	20 Sep 2020 23:50:24

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:50:22', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e1e0c733-eb41-4b57-85cb-12662b89b476' User entered '20 Sep 2020 19:50'	System	20 Sep 2020 23:50:24
	System	20 Sep 2020 23:50:24

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 4'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:39:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:51:08', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '19b6aeed-1187-43d2-8e28-5d04b0f330dd' User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'	System	22 Sep 2020 01:52:02



US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:39:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:51:14', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '19b6aeed-1187-43d2-8e28-5d04b0f330dd' User entered 'No (N)'	System	22 Sep 2020 01:52:02
	System	22 Sep 2020 01:52:02

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:39:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:51:21', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '19b6aeed-1187-43d2-8e28-5d04b0f330dd' User entered 'No (N)'	System	22 Sep 2020 01:52:02
	System	22 Sep 2020 01:52:02

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:39:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:51:48', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '19b6aeed-1187-43d2-8e28-5d04b0f330dd'	System	22 Sep 2020 01:52:02
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		22 Sep 2020 01:52:02

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:52:00', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '19b6aeed-1187-43d2-8e28-5d04b0f330dd' User entered '21 Sep 2020 21:52'	System	22 Sep 2020 01:52:02
	System	22 Sep 2020 01:52:02

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 5'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:39:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:00:40', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '34829713-73b6-4ae9-8939-0c5bd9f00719' User entered 'None (1)'	System	23 Sep 2020 03:01:22
	System	23 Sep 2020 03:01:22



US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:39:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:00:45', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '34829713-73b6-4ae9-8939-0c5bd9f00719' User entered 'No (N)'	System	23 Sep 2020 03:01:22
	System	23 Sep 2020 03:01:22

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:39:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:00:53', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '34829713-73b6-4ae9-8939-0c5bd9f00719' User entered 'No (N)'	System	23 Sep 2020 03:01:22
	System	23 Sep 2020 03:01:22

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:39:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:00:58', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '34829713-73b6-4ae9-8939-0c5bd9f00719' User entered 'None (1)'	System	23 Sep 2020 03:01:22
	System	23 Sep 2020 03:01:22

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:01:19', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '34829713-73b6-4ae9-8939-0c5bd9f00719' User entered '22 Sep 2020 23:01'	System	23 Sep 2020 03:01:22
	System	23 Sep 2020 03:01:22

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 6'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:39:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:54:52', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'b24077cc-ccbf-4343-a075-731100955418' User entered 'None (1)'	System	24 Sep 2020 01:55:28
	System	24 Sep 2020 01:55:28



US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:39:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:54:56', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'b24077cc-ccbf-4343-a075-731100955418' User entered 'No (N)'	System	24 Sep 2020 01:55:28
	System	24 Sep 2020 01:55:28

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:39:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:55:06', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'b24077cc-ccbf-4343-a075-731100955418' User entered 'No (N)'	System	24 Sep 2020 01:55:28
	System	24 Sep 2020 01:55:28

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:39:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:55:10', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'b24077cc-ccbf-4343-a075-731100955418' User entered 'None (1)'	System	24 Sep 2020 01:55:28
	System	24 Sep 2020 01:55:28

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:55:26', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'b24077cc-ccbf-4343-a075-731100955418' User entered '23 Sep 2020 21:55'	System	24 Sep 2020 01:55:28
	System	24 Sep 2020 01:55:28

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 7'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:39:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:40:00', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '8fd52aa1-da04-4c56-b168-9e0ee435dab9' User entered 'None (1)'	System	25 Sep 2020 00:40:28
	System	25 Sep 2020 00:40:28



US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:39:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:40:05', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '8fd52aa1-da04-4c56-b168-9e0ee435dab9' User entered 'No (N)'	System	25 Sep 2020 00:40:28
	System	25 Sep 2020 00:40:28

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:39:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:40:13', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '8fd52aa1-da04-4c56-b168-9e0ee435dab9' User entered 'No (N)'	System	25 Sep 2020 00:40:28
	System	25 Sep 2020 00:40:28

US3952116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:39:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:40:17', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '8fd52aa1-da04-4c56-b168-9e0ee435dab9' User entered 'None (1)'	System	25 Sep 2020 00:40:28
	System	25 Sep 2020 00:40:28

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:40:24', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '8fd52aa1-da04-4c56-b168-9e0ee435dab9' User entered '24 Sep 2020 20:40'	System	25 Sep 2020 00:40:28
	System	25 Sep 2020 00:40:28

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:39:34**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:46:41', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '4509a6f7-c93d-4453-a789-eb261592cbc8' User entered 'None (0)'	System	18 Sep 2020 21:47:31
	System	18 Sep 2020 21:47:31



**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:39:34**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:46:47', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '4509a6f7-c93d-4453-a789-eb261592cbc8' User entered 'None (0)'	System	18 Sep 2020 21:47:31
	System	18 Sep 2020 21:47:31

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:46:51', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '4509a6f7-c93d-4453-a789-eb261592cbc8' User entered 'None (0)'	System	18 Sep 2020 21:47:31
	System	18 Sep 2020 21:47:31

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:46:56', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '4509a6f7-c93d-4453-a789-eb261592cbc8' User entered 'None (0)'	System	18 Sep 2020 21:47:31
	System	18 Sep 2020 21:47:31

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:47:00', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '4509a6f7-c93d-4453-a789-eb261592cbc8' User entered 'None (0)'	System	18 Sep 2020 21:47:31
	System	18 Sep 2020 21:47:31

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:39:34**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:47:03', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '4509a6f7-c93d-4453-a789-eb261592cbc8' User entered 'None (0)'	System	18 Sep 2020 21:47:31
	System	18 Sep 2020 21:47:31

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:39:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:47:12', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '4509a6f7-c93d-4453-a789-eb261592cbc8' User entered 'No (N)'	System	18 Sep 2020 21:47:31
	System	18 Sep 2020 21:47:31

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-18T17:47:25', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '4509a6f7-c93d-4453-a789-eb261592cbc8' User entered '18 Sep 2020 17:47'	System	18 Sep 2020 21:47:31
	System	18 Sep 2020 21:47:31

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '18 Sep 2020 17:09'	System	18 Sep 2020 21:30:27



**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '18 Sep 2020 19:39'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59



US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:39:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:20:59

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '18 Sep 2020 20:34'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 2'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:48:17', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7f5c3ee4-7be8-4344-b780-6d22c399df4e' User entered 'None (0)'	System	20 Sep 2020 01:49:54
	System	20 Sep 2020 01:49:54

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:39:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:48:28', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7f5c3ee4-7be8-4344-b780-6d22c399df4e' User entered 'None (0)'	System	20 Sep 2020 01:49:54
	System	20 Sep 2020 01:49:54

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:39:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:49:42', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7f5c3ee4-7be8-4344-b780-6d22c399df4e' User entered 'None (0)'	System	20 Sep 2020 01:49:54
	System	20 Sep 2020 01:49:54



**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:48:39', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7f5c3ee4-7be8-4344-b780-6d22c399df4e' User entered 'None (0)'	System	20 Sep 2020 01:49:54
	System	20 Sep 2020 01:49:54

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:48:44', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7f5c3ee4-7be8-4344-b780-6d22c399df4e' User entered 'None (0)'	System	20 Sep 2020 01:49:54
	System	20 Sep 2020 01:49:54

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:48:48', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7f5c3ee4-7be8-4344-b780-6d22c399df4e' User entered 'None (0)'	System	20 Sep 2020 01:49:54
	System	20 Sep 2020 01:49:54

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:39:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:49:10', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7f5c3ee4-7be8-4344-b780-6d22c399df4e' User entered 'No (N)'	System	20 Sep 2020 01:49:54
	System	20 Sep 2020 01:49:54

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-19T21:49:49', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7f5c3ee4-7be8-4344-b780-6d22c399df4e' User entered '19 Sep 2020 21:49'	System	20 Sep 2020 01:49:54
	System	20 Sep 2020 01:49:54

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 3'	System	18 Sep 2020 21:30:27



**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:51:06', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '077c9492-16f2-4054-a7d3-a1cc3d7e6276' User entered 'None (0)'	System	20 Sep 2020 23:52:24
	System	20 Sep 2020 23:52:24

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:51:17', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '077c9492-16f2-4054-a7d3-a1cc3d7e6276' User entered 'None (0)'	System	20 Sep 2020 23:52:24
	System	20 Sep 2020 23:52:24

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:39:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:51:24', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '077c9492-16f2-4054-a7d3-a1cc3d7e6276' User entered 'None (0)'	System	20 Sep 2020 23:52:24
	System	20 Sep 2020 23:52:24

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:39:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:51:29', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '077c9492-16f2-4054-a7d3-a1cc3d7e6276' User entered 'None (0)'	System	20 Sep 2020 23:52:24
	System	20 Sep 2020 23:52:24

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:51:34', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '077c9492-16f2-4054-a7d3-a1cc3d7e6276' User entered 'None (0)'	System	20 Sep 2020 23:52:24
	System	20 Sep 2020 23:52:24

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:51:38', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '077c9492-16f2-4054-a7d3-a1cc3d7e6276' User entered 'None (0)'	System	20 Sep 2020 23:52:24
	System	20 Sep 2020 23:52:24

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:39:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:51:52', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '077c9492-16f2-4054-a7d3-a1cc3d7e6276' User entered 'No (N)'	System	20 Sep 2020 23:52:24
	System	20 Sep 2020 23:52:24

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-20T19:52:21', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '077c9492-16f2-4054-a7d3-a1cc3d7e6276' User entered '20 Sep 2020 19:52'	System	20 Sep 2020 23:52:24
	System	20 Sep 2020 23:52:24



**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 4'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:39:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:52:17', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '1a125fed-a966-4c1d-a081-33981d6a8545'	System	22 Sep 2020 01:53:40
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		22 Sep 2020 01:53:40

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:52:25', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '1a125fed-a966-4c1d-a081-33981d6a8545' User entered 'None (0)'	System	22 Sep 2020 01:53:40
	System	22 Sep 2020 01:53:40

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:39:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:52:30', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '1a125fed-a966-4c1d-a081-33981d6a8545' User entered 'None (0)'	System	22 Sep 2020 01:53:40
	System	22 Sep 2020 01:53:40

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:39:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:52:36', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '1a125fed-a966-4c1d-a081-33981d6a8545' User entered 'None (0)'	System	22 Sep 2020 01:53:40
	System	22 Sep 2020 01:53:40

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:52:40', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '1a125fed-a966-4c1d-a081-33981d6a8545' User entered 'None (0)'	System	22 Sep 2020 01:53:40
	System	22 Sep 2020 01:53:40



**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:52:44', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '1a125fed-a966-4c1d-a081-33981d6a8545' User entered 'None (0)'	System	22 Sep 2020 01:53:40
	System	22 Sep 2020 01:53:40

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:39:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:52:59', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '1a125fed-a966-4c1d-a081-33981d6a8545' User entered 'No (N)'	System	22 Sep 2020 01:53:40
	System	22 Sep 2020 01:53:40

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-21T21:53:13', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '1a125fed-a966-4c1d-a081-33981d6a8545' User entered '21 Sep 2020 21:53'	System	22 Sep 2020 01:53:40
	System	22 Sep 2020 01:53:40

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 5'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:01:35', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '616a228a-b952-4073-8a21-3d58a032b1f8' User entered 'None (0)'	System	23 Sep 2020 03:02:31
	System	23 Sep 2020 03:02:31

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:01:44', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '616a228a-b952-4073-8a21-3d58a032b1f8' User entered 'None (0)'	System	23 Sep 2020 03:02:31
	System	23 Sep 2020 03:02:31



US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:39:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:01:50', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '616a228a-b952-4073-8a21-3d58a032b1f8' User entered 'None (0)'	System	23 Sep 2020 03:02:31
	System	23 Sep 2020 03:02:31

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:39:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:01:55', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '616a228a-b952-4073-8a21-3d58a032b1f8' User entered 'None (0)'	System	23 Sep 2020 03:02:31
	System	23 Sep 2020 03:02:31

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:02:06', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '616a228a-b952-4073-8a21-3d58a032b1f8' User entered 'None (0)'	System	23 Sep 2020 03:02:31
	System	23 Sep 2020 03:02:31

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:02:09', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '616a228a-b952-4073-8a21-3d58a032b1f8' User entered 'None (0)'	System	23 Sep 2020 03:02:31
	System	23 Sep 2020 03:02:31

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:39:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:02:16', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '616a228a-b952-4073-8a21-3d58a032b1f8' User entered 'No (N)'	System	23 Sep 2020 03:02:31
	System	23 Sep 2020 03:02:31

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-22T23:02:26', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '616a228a-b952-4073-8a21-3d58a032b1f8' User entered '22 Sep 2020 23:02'	System	23 Sep 2020 03:02:31
	System	23 Sep 2020 03:02:31

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 21:30:27



**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 6'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:55:39', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '87310df4-02c3-45a7-954c-297ca7d3120c' User entered 'None (0)'	System	24 Sep 2020 01:56:25
	System	24 Sep 2020 01:56:25

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:39:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:55:44', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '87310df4-02c3-45a7-954c-297ca7d3120c' User entered 'None (0)'	System	24 Sep 2020 01:56:25
	System	24 Sep 2020 01:56:25

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:39:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:55:55', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '87310df4-02c3-45a7-954c-297ca7d3120c' User entered 'None (0)'	System	24 Sep 2020 01:56:25
	System	24 Sep 2020 01:56:25

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:39:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:55:59', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '87310df4-02c3-45a7-954c-297ca7d3120c' User entered 'None (0)'	System	24 Sep 2020 01:56:25
	System	24 Sep 2020 01:56:25

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:39:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:56:05', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '87310df4-02c3-45a7-954c-297ca7d3120c' User entered 'None (0)'	System	24 Sep 2020 01:56:25
	System	24 Sep 2020 01:56:25

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:56:11', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '87310df4-02c3-45a7-954c-297ca7d3120c' User entered 'None (0)'	System	24 Sep 2020 01:56:25
	System	24 Sep 2020 01:56:25

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:39:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:56:16', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '87310df4-02c3-45a7-954c-297ca7d3120c' User entered 'No (N)'	System	24 Sep 2020 01:56:25
	System	24 Sep 2020 01:56:25



**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-23T21:56:23', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '87310df4-02c3-45a7-954c-297ca7d3120c' User entered '23 Sep 2020 21:56'	System	24 Sep 2020 01:56:25
	System	24 Sep 2020 01:56:25

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:39:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 7'	System	18 Sep 2020 21:30:27

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:39:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:40:31', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e51daa97-ced0-4f4c-a3c2-3096a57bd0cf' User entered 'None (0)'	System	25 Sep 2020 00:41:04
	System	25 Sep 2020 00:41:04

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:39:34**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:40:35', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e51daa97-ced0-4f4c-a3c2-3096a57bd0cf' User entered 'None (0)'	System	25 Sep 2020 00:41:04
	System	25 Sep 2020 00:41:04

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:39:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:40:39', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e51daa97-ced0-4f4c-a3c2-3096a57bd0cf' User entered 'None (0)'	System	25 Sep 2020 00:41:04
	System	25 Sep 2020 00:41:04

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:39:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:40:42', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e51daa97-ced0-4f4c-a3c2-3096a57bd0cf' User entered 'None (0)'	System	25 Sep 2020 00:41:04
	System	25 Sep 2020 00:41:04



**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:39:34**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:40:46', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e51daa97-ced0-4f4c-a3c2-3096a57bd0cf' User entered 'None (0)'	System	25 Sep 2020 00:41:04
	System	25 Sep 2020 00:41:04

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:39:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:40:50', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e51daa97-ced0-4f4c-a3c2-3096a57bd0cf' User entered 'None (0)'	System	25 Sep 2020 00:41:04
	System	25 Sep 2020 00:41:04

US3952116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:39:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:40:54', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e51daa97-ced0-4f4c-a3c2-3096a57bd0cf' User entered 'No (N)'	System	25 Sep 2020 00:41:04
	System	25 Sep 2020 00:41:04

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-09-24T20:41:02', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'e51daa97-ced0-4f4c-a3c2-3096a57bd0cf' User entered '24 Sep 2020 20:41'	System	25 Sep 2020 00:41:04
	System	25 Sep 2020 00:41:04

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:39:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:59
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:57:15

**US3952116**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered '28 Sep 2020'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:57:15



**US3952116**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:57:15

**US3952116**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered empty.	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:57:15

**US3952116**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:57:20

**US3952116**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'I'	System	29 Sep 2020 18:57:20

**US3952116**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 15:02:21

**US3952116**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered '02 Oct 2020'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 15:02:21

**US3952116**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 15:02:21

**US3952116**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered empty.	(b) (4) Nick Bart (b) (4)	05 Oct 2020 15:02:21



**US3952116**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:50:14
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	05 Oct 2020 15:03:03

**US3952116**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:30:34
User entered 'I'	System	05 Oct 2020 15:03:03

**US3952116**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:34:54
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	12 Oct 2020 18:34:41

**US3952116**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:34:54
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered '09 Oct 2020'	(b) (4) Nick Bart (b) (4)	12 Oct 2020 18:34:41

**US3952116**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:34:54
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4)	12 Oct 2020 18:34:41

**US3952116**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:34:54
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered empty.	(b) (4) Nick Bart (b) (4)	12 Oct 2020 18:34:41

**US3952116**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:34:54
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	12 Oct 2020 18:34:28

**US3952116**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:34:54
User entered '1'	System	12 Oct 2020 18:34:28



**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:49:23

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '23 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:49:23

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:49:23

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered 'VISIT2'	System	27 Oct 2020 18:49:23

US3952116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '23 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '14:35'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35



**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered '23 Oct 2020 14:35'	System	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '37.5' C	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

US3952116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '77'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered 'bpm'	System	27 Oct 2020 18:53:35

US3952116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
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 09:19:38
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 20:28:15
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)	12 Nov 2020 07:45:15
User entered '24'	Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered 'breaths/min'	System	27 Oct 2020 18:53:35



US3952116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4)	05 Jan 2021 09:20:18
Query 'Per CDM: Per CCG V2.0 page 50, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'CS reported' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 20:09:15
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:44:50
User entered '156'	Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered 'mmHg'	System	27 Oct 2020 18:53:35

US3952116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '86'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered 'mmHg'	System	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	27 Oct 2020 18:53:35

US3952116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User closed query 'Per CDM: Were vital signs assessed?' is recorded as 'No', however, per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 09:20:42
Query 'Per CDM: Were vital signs assessed?' is recorded as 'No', however, per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection. Please clarify and update as appropriate.' answered with 'Subject did not receive vaccination' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 20:10:05
User opened query 'Per CDM: Were vital signs assessed?' is recorded as 'No', however, per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:43:52
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35



**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	27 Oct 2020 18:53:35

US3952116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

US3952116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

US3952116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	27 Oct 2020 18:53:35



**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	27 Oct 2020 18:53:35

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:39:34**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:49:49

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:39:34**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '23 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:49:49

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:02

US3952116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:02



US3952116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:02

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	27 Oct 2020 18:54:02

US3952116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:02

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:02

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	27 Oct 2020 18:54:02

US3952116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:02

US3952116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	27 Oct 2020 18:54:02

US3952116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	27 Oct 2020 18:54:02



**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:51:13

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '23 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:51:13

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '15:36'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:51:13

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered '23 Oct 2020 15:36'	System	27 Oct 2020 18:51:13

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 12 Aug 2021 13:39:34**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '23 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:51:45

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4)	27 Oct 2020 18:51:45

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:51:45

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:39:34**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered '15:35'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:51:45



**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered '23 Oct 2020 15:35'	System	27 Oct 2020 18:51:45

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4)	27 Oct 2020 18:51:45

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:51:45

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:39:34**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:51:45

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	27 Oct 2020 18:51:45

US3952116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:49:28

**US3952116**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered 'I'	System	27 Oct 2020 18:49:28

**US3952116**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Yes (Y)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	06 Nov 2020 22:59:44



**US3952116**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered '30 Oct 2020'	Stephanie Melton (b) (4)	06 Nov 2020 22:59:44

**US3952116**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Contact Made (CONTACT MADE)'	Stephanie Melton (b) (4)	06 Nov 2020 22:59:44

**US3952116**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered empty.	(b) (4) Stephanie Melton (b) (4) (b) (4)	06 Nov 2020 22:59:44

**US3952116**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Yes (Y)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	06 Nov 2020 22:59:49

**US3952116**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered 'I'	System	06 Nov 2020 22:59:49

**US3952116**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Yes (Y)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	06 Nov 2020 23:00:00

**US3952116**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered '06 Nov 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 18:47:28
User entered '6 Nov 2020'	Nick Bart (b) (4)	06 Nov 2020 23:00:00
	Stephanie Melton (b) (4)	
	(b) (4)	

**US3952116**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Contact Made (CONTACT MADE)'	Stephanie Melton (b) (4)	06 Nov 2020 23:00:00



**US3952116**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered empty.	Stephanie Melton (b) (4)	06 Nov 2020 23:00:00

**US3952116**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Yes (Y)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	06 Nov 2020 23:00:14

**US3952116**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered 'I'	System	06 Nov 2020 23:00:14

**US3952116**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Yes (Y)'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 16:31:40

US3952116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18NOV2020 is reported under Visit 3 Day 57 in PPD portal; however, immunogenicity sample is missing in EDC. Kindly review if immuno sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 11:44:34
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18NOV2020 is reported under Visit 3 Day 57 in PPD portal; however, immunogenicity sample is missing in EDC. Kindly review if immuno sample was collected, if yes, update the data as appropriate, else clarify. ' answered with 'done' (Site from DM).	Nick Bart (b) (4)	10 Dec 2020 20:36:06
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18NOV2020 is reported under Visit 3 Day 57 in PPD portal; however, immunogenicity sample is missing in EDC. Kindly review if immuno sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 07:26:37
User entered '13 Nov 2020'	chrishea Harvey (b) (4)	17 Nov 2020 16:31:40

**US3952116**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 16:31:40

US3952116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered empty.	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 16:31:40

US3952116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:47:02
User entered 'Yes (Y)'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 16:30:58



**US3952116**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered 'I'	System	17 Nov 2020 16:30:58

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:22

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered '18 Nov 2020'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:22

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:22

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered 'VISIT3'	System	10 Dec 2020 20:36:22

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:28

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:28

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:28



**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	10 Dec 2020 20:36:28

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:28

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:28

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:28

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:28

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	10 Dec 2020 20:36:28

US3952116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:28

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	10 Dec 2020 20:36:28



**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:28

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	10 Dec 2020 20:36:28

US3952116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:28

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered empty.	System	10 Dec 2020 20:36:28

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36

US3952116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:32

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:39:34**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:32



**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:42

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered '18 Nov 2020'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:42

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:53
User entered '15:26'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:42

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered '18 Nov 2020 15:26'	System	10 Dec 2020 20:36:42

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 21:52:50
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	10 Dec 2020 20:36:46

**US3952116**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered 'I'	System	10 Dec 2020 20:36:46

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20
Data entry locked.	System	18 Sep 2020 21:30:27
User entered 'Day 64'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20
Data entry locked.	System	18 Sep 2020 21:30:27
User entered '18 Nov 2020 00:01'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:42:20
Data entry locked.	System	18 Sep 2020 21:30:27
User entered '22 Nov 2020 23:59'	System	18 Sep 2020 21:30:27

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-11-25T17:54:36', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '171e1437-379d-482d-a66c-b3b0fe8f7f10'	System	25 Nov 2020 22:55:18
User entered 'No (N)'	System	25 Nov 2020 22:55:18

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-11-25T17:54:46', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '171e1437-379d-482d-a66c-b3b0fe8f7f10'	System	25 Nov 2020 22:55:18
User entered 'No (N)'	System	25 Nov 2020 22:55:18

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-11-25T17:55:15', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '171e1437-379d-482d-a66c-b3b0fe8f7f10'	System	25 Nov 2020 22:55:18
User entered '25 Nov 2020 17:55:15'	System	25 Nov 2020 22:55:18

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-02T17:26:38', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '53a00ef8-ca84-4ad9-a9fc-c51d2fc7052f' User entered 'No (N)'	System	02 Dec 2020 22:27:08

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-02T17:26:53', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '53a00ef8-ca84-4ad9-a9fc-c51d2fc7052f' User entered 'No (N)'	System	02 Dec 2020 22:27:08

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-02T17:27:04', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '53a00ef8-ca84-4ad9-a9fc-c51d2fc7052f' User entered '02 Dec 2020 17:27:04'	System	02 Dec 2020 22:27:08
	System	02 Dec 2020 22:27:08

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-09T20:58:34', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7b1fbacf-e70d-4b5e-95c4-6b37d78380b8' User entered 'No (N)'	System	10 Dec 2020 01:59:18
	System	10 Dec 2020 01:59:18



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-09T20:58:46', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7b1fbacf-e70d-4b5e-95c4-6b37d78380b8' User entered 'No (N)'	System	10 Dec 2020 01:59:18
	System	10 Dec 2020 01:59:18

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-09T20:59:14', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7b1fbacf-e70d-4b5e-95c4-6b37d78380b8' User entered '09 Dec 2020 20:59:14'	System	10 Dec 2020 01:59:18
	System	10 Dec 2020 01:59:18

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-14T01:29:49', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '146bfdea-1f58-475b-a074-d1221c7b2e8b' User entered 'No (N)'	System	14 Dec 2020 06:30:45
	System	14 Dec 2020 06:30:45

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-14T01:30:03', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '146bfdea-1f58-475b-a074-d1221c7b2e8b'	System	14 Dec 2020 06:30:45
User entered 'No (N)'	System	14 Dec 2020 06:30:45

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-14T01:30:43', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '146bfdea-1f58-475b-a074-d1221c7b2e8b' User entered '14 Dec 2020 01:30:43'	System	14 Dec 2020 06:30:45
	System	14 Dec 2020 06:30:45



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-20T01:18:37', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'f686ad11-56f0-4c3d-a872-f482793e22d2'	System	20 Dec 2020 06:19:45
User entered 'No (N)'	System	20 Dec 2020 06:19:45

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-20T01:18:54', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'f686ad11-56f0-4c3d-a872-f482793e22d2'	System	20 Dec 2020 06:19:45
User entered 'No (N)'	System	20 Dec 2020 06:19:45

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-20T01:19:43', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'f686ad11-56f0-4c3d-a872-f482793e22d2' User entered '20 Dec 2020 01:19:43'	System	20 Dec 2020 06:19:45
	System	20 Dec 2020 06:19:45

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-27T00:35:23', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'd0de14ea-613c-4c11-8bbb-61c78455e44b' User entered 'No (N)'	System	27 Dec 2020 05:36:30
	System	27 Dec 2020 05:36:30

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-27T00:35:38', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'd0de14ea-613c-4c11-8bbb-61c78455e44b' User entered 'No (N)'	System	27 Dec 2020 05:36:30
	System	27 Dec 2020 05:36:30

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2020-12-27T00:36:27', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'd0de14ea-613c-4c11-8bbb-61c78455e44b' User entered '27 Dec 2020 00:36:27'	System	27 Dec 2020 05:36:30
	System	27 Dec 2020 05:36:30

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-03T06:00:38', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '35ba99e1-838a-4e57-b1db-386c818110d9'	System	03 Jan 2021 11:01:39
User entered 'No (N)'	System	03 Jan 2021 11:01:39



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-03T06:00:54', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '35ba99e1-838a-4e57-b1db-386c818110d9'	System	03 Jan 2021 11:01:39
User entered 'No (N)'	System	03 Jan 2021 11:01:39

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-03T06:01:37', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '35ba99e1-838a-4e57-b1db-386c818110d9' User entered '03 Jan 2021 06:01:37'	System	03 Jan 2021 11:01:39
	System	03 Jan 2021 11:01:39

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-10T18:06:52', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '72daab67-cf13-461a-b91b-d675a3abc621' User entered 'No (N)'	System	10 Jan 2021 23:07:52

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-10T18:07:08', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '72daab67-cf13-461a-b91b-d675a3abc621' User entered 'No (N)'	System	10 Jan 2021 23:07:52

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-10T18:07:48', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '72daab67-cf13-461a-b91b-d675a3abc621' User entered '10 Jan 2021 18:07:48'	System	10 Jan 2021 23:07:52
	System	10 Jan 2021 23:07:52



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-17T07:36:11', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '921b9b4c-c86d-44fa-aea3-0116dcf4cb15'	System	17 Jan 2021 12:37:04
User entered 'No (N)'	System	17 Jan 2021 12:37:04

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-17T07:36:29', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '921b9b4c-c86d-44fa-aea3-0116dcf4cb15'	System	17 Jan 2021 12:37:04
User entered 'No (N)'	System	17 Jan 2021 12:37:04

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-17T07:37:00', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '921b9b4c-c86d-44fa-aea3-0116dcf4cb15' User entered '17 Jan 2021 07:37:00'	System	17 Jan 2021 12:37:04
	System	17 Jan 2021 12:37:04

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-24T04:50:23', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '56ade123-440a-4dd1-a614-3be4adeaf6c6'	System	24 Jan 2021 09:50:59
User entered 'No (N)'	System	24 Jan 2021 09:50:59

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-24T04:50:36', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '56ade123-440a-4dd1-a614-3be4adeaf6c6'	System	24 Jan 2021 09:50:59
User entered 'No (N)'	System	24 Jan 2021 09:50:59

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-24T04:50:56', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '56ade123-440a-4dd1-a614-3be4adeaf6c6' User entered '24 Jan 2021 04:50:56'	System	24 Jan 2021 09:50:59
	System	24 Jan 2021 09:50:59

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-31T20:57:18', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '19b5f75b-a602-4e8e-b6af-8d0d1d6c6135'	System	01 Feb 2021 01:58:11
User entered 'No (N)'	System	01 Feb 2021 01:58:11



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-31T20:57:32', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '19b5f75b-a602-4e8e-b6af-8d0d1d6c6135'	System	01 Feb 2021 01:58:11
User entered 'No (N)'	System	01 Feb 2021 01:58:11

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-01-31T20:58:09', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '19b5f75b-a602-4e8e-b6af-8d0d1d6c6135' User entered '31 Jan 2021 20:58:09'	System	01 Feb 2021 01:58:11
	System	01 Feb 2021 01:58:11

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-07T01:05:57', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'c92b79e9-7f09-4675-a61e-1c9cc33fde9a' User entered 'No (N)'	System	07 Feb 2021 06:06:40
	System	07 Feb 2021 06:06:40

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-07T01:06:10', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'c92b79e9-7f09-4675-a61e-1c9cc33fde9a' User entered 'No (N)'	System	07 Feb 2021 06:06:40
	System	07 Feb 2021 06:06:40

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-07T01:06:36', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'c92b79e9-7f09-4675-a61e-1c9cc33fde9a' User entered '07 Feb 2021 01:06:36'	System	07 Feb 2021 06:06:40
	System	07 Feb 2021 06:06:40



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-14T00:15:29', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7a16f7e7-7fb1-4f24-88cf-d3b5ba32e70a' User entered 'No (N)'	System	14 Feb 2021 05:16:16
	System	14 Feb 2021 05:16:16

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-14T00:15:43', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7a16f7e7-7fb1-4f24-88cf-d3b5ba32e70a' User entered 'No (N)'	System	14 Feb 2021 05:16:16
	System	14 Feb 2021 05:16:16

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-14T00:16:14', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '7a16f7e7-7fb1-4f24-88cf-d3b5ba32e70a' User entered '14 Feb 2021 00:16:14'	System	14 Feb 2021 05:16:16
	System	14 Feb 2021 05:16:16

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-21T00:29:36', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'f5f7fe48-52a2-4574-abaa-f6d4e144b904'	System	21 Feb 2021 05:30:07
User entered 'No (N)'	System	21 Feb 2021 05:30:07

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-21T00:29:48', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'f5f7fe48-52a2-4574-abaa-f6d4e144b904' User entered 'No (N)'	System	21 Feb 2021 05:30:07
	System	21 Feb 2021 05:30:07

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-21T00:30:05', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: 'f5f7fe48-52a2-4574-abaa-f6d4e144b904'	System	21 Feb 2021 05:30:07
User entered '21 Feb 2021 00:30:05'	System	21 Feb 2021 05:30:07

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-28T00:59:16-05:00', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '2692fb8d-1c20-4f03-8c76-ecd9fa7e676b'	System	28 Feb 2021 06:00:03
User entered 'No (N)'	System	28 Feb 2021 06:00:03



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-28T00:59:28-05:00', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '2692fb8d-1c20-4f03-8c76-ecd9fa7e676b'	System	28 Feb 2021 06:00:03
User entered 'No (N)'	System	28 Feb 2021 06:00:03

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-28T00:59:43-05:00', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '2692fb8d-1c20-4f03-8c76-ecd9fa7e676b'	System	28 Feb 2021 06:00:03
User entered '28 Feb 2021 05:59:43'	System	28 Feb 2021 06:00:03

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:42:20



**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 09:42:20

**US3952116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:39:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:42:20
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 09:42:20

US3952116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:39:34

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-28T01:00:01-05:00', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '42596288-f7f8-46ea-8b08-3458fd27f52a' User entered 'No (N)'	System	28 Feb 2021 06:00:43
	System	28 Feb 2021 06:00:43

**US3952116**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:55:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D9766F3C-A8DC-420F-9147-C303F786298E)', Time: '2021-02-28T01:00:16-05:00', User OID: 'PatientReportedOutcome (US3952116)', ODM File OID: '42596288-f7f8-46ea-8b08-3458fd27f52a' User entered '28 Feb 2021 06:00:16'	System	28 Feb 2021 06:00:43
	System	28 Feb 2021 06:00:43

**US3952116**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:44:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:04:28

**US3952116**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:44:23
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:04:28

**US3952116**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:44:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:04:28

**US3952116**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:44:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:04:28



**US3952116**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:44:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:04:35

**US3952116**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:36
User entered 'I'	System	22 Dec 2020 20:04:35

**US3952116**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:15:05

**US3952116**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:15:05

**US3952116**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:15:05

**US3952116**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:15:05

**US3952116**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:15:14

**US3952116**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User entered 'I'	System	19 Jan 2021 16:15:14



**US3952116**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:53:27

**US3952116**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:53:27

**US3952116**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:53:27

**US3952116**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:53:27

**US3952116**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:53:31

**US3952116**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User entered 'I'	System	02 Mar 2021 19:53:31

**US3952116**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:05:28

**US3952116**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '22 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	26 Mar 2021 16:46:49
User entered '01 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 20:05:28



**US3952116**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:05:28

**US3952116**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:05:28

**US3952116**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:05:33

**US3952116**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:00:37
User entered 'I'	System	02 Mar 2021 20:05:33

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4)	28 Jan 2021 17:52:24

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '21 Jan 2021'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Jan 2021 17:52:24

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Clinic (Clinic)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Jan 2021 17:52:24

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 17:52:24



**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:39:34**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '21 Jan 2021'	(b) (4) Atanas Filev (b) (4)	28 Jan 2021 17:52:53

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:39:34**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:43:39

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:39:34**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4)	28 Jan 2021 17:52:53

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:39:34**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
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 19:43:39

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:39:34**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '21 Jan 2021'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Jan 2021 17:52:53

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:39:34**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Placebo (Placebo)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Jan 2021 17:52:53

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:39:34**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Placebo (Placebo)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Jan 2021 17:52:53

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:39:34**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Not Administered (NA)'	(b) (4) Atanas Filev (b) (4)	28 Jan 2021 17:52:53



**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:39:34**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4)	28 Jan 2021 17:52:53

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:39:34**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered '1'	System	28 Jan 2021 17:52:53

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'I'	System	28 Jan 2021 17:52:53

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:39:34**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '68.5' in	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:39:34**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '157.0' lb	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:39:34**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered '23.57373'	System	28 Jan 2021 19:02:44
DataPoint set to visible.	System	28 Jan 2021 17:52:53

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:39:34**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '68.5' in	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:39:34**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '157.0' lb	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44



US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered '23.57373'	System	28 Jan 2021 19:02:44
DataPoint set to visible.	System	28 Jan 2021 17:52:53

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '21 Jan 2021'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '15:17'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered '21 Jan 2021 15:17'	System	28 Jan 2021 19:02:44

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '98.5' F	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44



**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '71'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'bpm'	System	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '16'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'breaths/min'	System	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '99'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'mmHg'	System	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '66'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44



**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'mmHg'	System	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:39:34**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '68.5' in	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:39:34**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '157.0' lb	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered '23.57373'	System	28 Jan 2021 19:02:44
DataPoint set to visible.	System	28 Jan 2021 17:52:53

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '21 Jan 2021'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '16:34'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44



**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered '21 Jan 2021 16:34'	System	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '98.6' F	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '72'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'bpm'	System	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '16'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'breaths/min'	System	28 Jan 2021 19:02:44



**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '112'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'mmHg'	System	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '80'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'mmHg'	System	28 Jan 2021 19:02:44

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:39:34**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:03:16

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:39:34**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:03:16

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:04:07

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:04:07



US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:04:07

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'mRNA-1273'	System	28 Jan 2021 19:04:07
DataPoint set to visible.	System	28 Jan 2021 17:52:53

US3952116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '21 Jan 2021'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:04:07

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '15:54'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:04:07

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered '21 Jan 2021 15:54'	System	28 Jan 2021 19:04:07

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Left Arm (LEFT ARM)'	Nick Bart (b) (4)	28 Jan 2021 19:04:07

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'ONCE'	System	28 Jan 2021 19:04:07

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 19:04:07



**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:04:19

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '21 Jan 2021'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:04:19

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '14:32'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:04:19

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered '21 Jan 2021 14:32'	System	28 Jan 2021 19:04:19

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:39:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:03:41

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:39:34**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '21 Jan 2021'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:03:41

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:39:34**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '14:34'	(b) (4) Nick Bart (b) (4)	28 Jan 2021 19:03:41

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:39:34**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered '21 Jan 2021 14:34'	System	28 Jan 2021 19:03:41



**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4)	28 Jan 2021 17:52:58

**US3952116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:10
User entered 'I'	System	28 Jan 2021 17:52:58

**US3952116**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:54
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Jan 2021 17:53:12

**US3952116**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:54
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '28 Jan 2021'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Jan 2021 17:53:12

**US3952116**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:54
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	28 Jan 2021 17:53:28
reason for change: Data Entry Error	Atanas Filev (b) (4)	28 Jan 2021 17:53:12
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	

US3952116

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:54
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	28 Jan 2021 17:53:28
Please review and reconcile.' (Site from System).	System	
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	28 Jan 2021 17:53:12
Please review and reconcile.' (Site from System).		
User entered empty.	Atanas Filev (b) (4)	28 Jan 2021 17:53:12
	(b) (4)	

**US3952116**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:54
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Jan 2021 17:53:17

**US3952116**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:54
User entered 'I'	System	28 Jan 2021 17:53:17



**US3952116**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:54
User entered '1'	System	28 Jan 2021 17:53:17
DataPoint set to visible.	System	28 Jan 2021 17:53:17

**US3952116**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:50:20

**US3952116**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:50:20

**US3952116**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:50:20

**US3952116**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'OLD29'	System	02 Mar 2021 14:50:20

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36



**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '14:32'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered '22 Feb 2021 14:32'	System	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '37.6' C	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '95'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'bpm'	System	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '12'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36



**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'breaths/min'	System	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '110'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'mmHg'	System	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '80'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'mmHg'	System	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

US3952116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	11 Mar 2021 14:03:08
User entered '22 Feb 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	11 Mar 2021 14:03:08
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 14:54:36
User entered '26 Feb 2021'	(b) (4), (b) (6)	02 Mar 2021 14:54:36



**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '15:30'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered '22 Feb 2021 15:30'	System	11 Mar 2021 14:03:08
User entered '26 Feb 2021 15:30'	System	02 Mar 2021 14:54:36

US3952116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '37.1' C	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '95'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'bpm'	System	02 Mar 2021 14:54:36

US3952116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '14'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36



**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'breaths/min'	System	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '135'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'mmHg'	System	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '81'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:54:36

**US3952116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'mmHg'	System	02 Mar 2021 14:54:36

US3952116

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	02 Mar 2021 14:58:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 14:58:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 14:58:15
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 14:57:59
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 14:57:59

**US3952116**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:39:34**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:57:59

**US3952116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:59:21



**US3952116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:59:21

US3952116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:59:21

**US3952116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'mRNA-1273'	System	02 Mar 2021 14:59:21
DataPoint set to visible.	System	28 Jan 2021 17:53:17

US3952116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:59:21

**US3952116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '14:53'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:59:21

**US3952116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered '22 Feb 2021 14:53'	System	02 Mar 2021 14:59:21

US3952116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:59:21

**US3952116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'ONCE'	System	02 Mar 2021 14:59:21



**US3952116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:39:34**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 14:59:21

US3952116

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:59:37

**US3952116**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:26:12
User entered 'I'	System	02 Mar 2021 14:59:37

**US3952116**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:34:18
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:54:48

**US3952116**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:34:18
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:54:48

**US3952116**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:34:18
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:54:48

**US3952116**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:39:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:34:18
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:54:48

**US3952116**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:34:18
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:54:52



**US3952116**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:39:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:34:18
User entered 'I'	System	02 Mar 2021 19:54:52

**US3952116**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:47:55

**US3952116**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:47:55

**US3952116**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:47:55

**US3952116**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:39:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User entered 'OLD57'	System	26 Mar 2021 16:47:55

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '14:14'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:48:38



**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User entered '22 Mar 2021 14:14'	System	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '91'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User entered 'bpm'	System	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '12'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User entered 'breaths/min'	System	26 Mar 2021 16:48:38



**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '104'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User entered 'mmHg'	System	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '75'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User entered 'mmHg'	System	26 Mar 2021 16:48:38

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 08:32:09

**US3952116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 08:32:09

**US3952116**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:39:34**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:48:49

**US3952116**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:39:34**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:48:49



**US3952116**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:49:04

US3952116

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:49:04

**US3952116**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '14:22'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:49:04

**US3952116**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:32:09
User entered '22 Mar 2021 14:22'	System	26 Mar 2021 16:49:04

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '23 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:24

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '0'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:24

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'I'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:24

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '0'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:24



**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 12 Aug 2021 13:39:34**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:52
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '0'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:24

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '23 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '15:53'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User entered '23 Oct 2020 15:53'	System	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:49



**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '75'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User entered 'bpm'	System	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User entered 'breaths/min'	System	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '142'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User entered 'mmHg'	System	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User entered '88'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:54:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:20:49
User entered 'mmHg'	System	27 Oct 2020 18:54:49



**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 01:20:49

**US3952116**

**Folder: Unscheduled 23 Oct 2020**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:39:34**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 01:20:49

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 12 Aug 2021 13:39:34**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:39:25
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:11:06
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:55:19

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08

US3952116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 19:00:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 19:00:27
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 18:59:59
User entered 'dehydration'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 18:59:32



US3952116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '22 Oct 2020'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User entered empty.	System	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '23 Oct 2020'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User entered empty.	System	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nick Bart (b) (4)	27 Oct 2020 18:59:32



US3952116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

US3952116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 18:59:32



**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

US3952116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	15 Feb 2021 20:39:16
User closed query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn" due to this AE#1 as confirmed in the previous query response. However, Dosing Discontinuation form (End of study folder) is not updated. Please review and update accordingly. Thank you.' (Site from DM).	Nick Bart (b) (4)	04 Dec 2020 11:44:43
Query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn" due to this AE#1 as confirmed in the previous query response. However, Dosing Discontinuation form (End of study folder) is not updated. Please review and update accordingly. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 21:30:12
User opened query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn" due to this AE#1 as confirmed in the previous query response. However, Dosing Discontinuation form (End of study folder) is not updated. Please review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:47:02
Query 'Per CDM Re-query: Per previous query response 'Dehydration was AE that caused withdrawal of IP' please review and confirm if the action taken 'Investigational Product Withdrawn' updated at AE#2 should be removed; else clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:46:33
User closed query 'Per CDM: Action taken with investigational product is 'Investigational Product Withdrawn', however, there is AE#2 with this same Action taken. Please determine which AE actually led to the investigational product being withdrawn and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:44:45

US3952116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:34

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM Re-query: Per previous query response 'Dehydration was AE that caused withdrawal of IP' please review and confirm if the action taken 'Investigational Product Withdrawn' updated at AE#2 should be removed; else clarify. ' (Site from DM). Un-reviewed for Data Management.	(b) (4), (b) (6)	13 Nov 2020 10:49:08
Reviewed for Data Management.	(b) (4), (b) (6)	13 Nov 2020 10:33:13
Query 'Per CDM: Action taken with investigational product is 'Investigational Product Withdrawn', however, there is AE#2 with this same Action taken. Please determine which AE actually led to the investigational product being withdrawn and update as appropriate. Thank you.' answered with 'Dehydration was AE that caused withdrawal of IP' (Site from DM).	Nick Bart (b) (4)	13 Nov 2020 10:33:09
User opened query 'Per CDM: Action taken with investigational product is 'Investigational Product Withdrawn', however, there is AE#2 with this same Action taken. Please determine which AE actually led to the investigational product being withdrawn and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:29:30
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Nick Bart (b) (4)	05 Nov 2020 13:23:12
		27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 18:59:32



US3952116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User closed query 'Per CDM: Other action taken is checked as 'Concomitant Medication', however, there are no corresponding medications recorded on the Prior and Concomitant Medications form with an Indication of 'Dehydration'. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 10:31:23
Query 'Per CDM: Other action taken is checked as 'Concomitant Medication', however, there are no corresponding medications recorded on the Prior and Concomitant Medications form with an Indication of 'Dehydration'. Please clarify and update as appropriate.' answered with 'NcCl added to CM' (Site from DM).	Nick Bart (b) (4)	10 Nov 2020 19:29:39
User opened query 'Per CDM: Other action taken is checked as 'Concomitant Medication', however, there are no corresponding medications recorded on the Prior and Concomitant Medications form with an Indication of 'Dehydration'. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:20:02
User entered 'I'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 18:59:32

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User entered '0'	System	27 Oct 2020 18:59:32

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:08
User entered '0'	System	27 Oct 2020 18:59:32

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 21:45:08



**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 13:00:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 13:00:50
User closed query 'Per CDM: Please note that HYPERTENSION is already reported on the MH eCRF. If the ELEVATED BLOOD PRESSURE "GRADE 3 BLOOD PRESSURE [INCREASE FROM BASELINE]" documented here is associated with the medical condition of HYPERTENSION, if Yes, Please consider if it would be appropriate to update "AE term" as "Worsening of pre-existing Hypertension". If not related to the MH, please clarify it in a query response. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:43:05
Data point term sent to Coder	System	03 Dec 2020 21:55:43
Query 'Per CDM: Please note that HYPERTENSION is already reported on the MH eCRF. If the ELEVATED BLOOD PRESSURE "GRADE 3 BLOOD PRESSURE [INCREASE FROM BASELINE]" documented here is associated with the medical condition of HYPERTENSION, if Yes, Please consider if it would be appropriate to update "AE term" as "Worsening of pre-existing Hypertension". If not related to the MH, please clarify it in a query response. Thank you.' answered with 'term updated' (Site from DM).	Nick Bart (b) (4)	03 Dec 2020 21:54:56
Coding entries removed.	Nick Bart (b) (4)	03 Dec 2020 21:54:52
User entered 'worsening of baseline elevated GRADE 3 BLOOD PRESSURE' reason for change: Data Entry Error	Nick Bart (b) (4)	03 Dec 2020 21:54:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:34

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please note that HYPERTENSION is already reported on the MH eCRF. If the ELEVATED BLOOD PRESSURE "GRADE 3 BLOOD PRESSURE [INCREASE FROM BASELINE]" documented here is associated with the medical condition of HYPERTENSION, if Yes, Please consider if it would be appropriate to update "AE term" as "Worsening of pre-existing Hypertension". If not related to the MH, please clarify it in a query response. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:38:28
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Blood pressure increased - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 06:02:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	11 Nov 2020 06:02:45
Data point term sent to Coder	System	10 Nov 2020 19:34:12
User entered 'GRADE 3 BLOOD PRESSURE [increase from baseline]' reason for change: Data Entry Error	Nick Bart (b) (4)	10 Nov 2020 19:33:56
User closed query 'For coding purposes, please specify if GRADE 3 BLOOD PRESSURE is an increase or decrease and update the term with your response' (Site from System).	System	10 Nov 2020 19:33:46
Query 'For coding purposes, please specify if GRADE 3 BLOOD PRESSURE is an increase or decrease and update the term with your response' answered with 'updated' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 19:33:46
User opened query 'For coding purposes, please specify if GRADE 3 BLOOD PRESSURE is an increase or decrease and update the term with your response' (Site from System).	Coder Import (b) (4)	31 Oct 2020 20:36:14
Data point term sent to Coder	System	27 Oct 2020 19:09:16
User entered 'grade 3 blood pressure'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '23 Oct 2020'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	27 Oct 2020 19:09:20
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	27 Oct 2020 19:09:20
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	27 Oct 2020 19:09:10
User entered '00:00'	Nick Bart (b) (4)	27 Oct 2020 19:09:10



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User entered empty.	System	27 Oct 2020 19:09:20
User entered '23 Oct 2020 00:00'	System	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '23 Oct 2020'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	27 Oct 2020 19:09:20
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	27 Oct 2020 19:09:20
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	27 Oct 2020 19:09:10
User entered '15:53'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User entered empty.	System	27 Oct 2020 19:09:20
User entered '23 Oct 2020 15:53'	System	27 Oct 2020 19:09:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:34

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade as AE term reflects this is GRADE 3. ' (Site from DM).	(b) (4)	05 Jan 2021 09:09:56
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade as AE term reflects this is GRADE 3. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 20:28:38
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Nick Bart (b) (4)	04 Jan 2021 20:28:33
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade as AE term reflects this is GRADE 3. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 05:36:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 19:09:10



**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 19:09:10



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User closed query 'Per CDM: Please check on Dosing Discontinuation form Primary reason for dosing discontinuation is mentioned as AE#1. Per CCG If reason for discontinuation is mentioned as AE then on same AE page 'Action taken with investigational product' must recorded/selected as 'Investigational product withdrawn'. Please reconcile the data and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:31:52
Query 'Per CDM: Please check on Dosing Discontinuation form Primary reason for dosing discontinuation is mentioned as AE#1. Per CCG If reason for discontinuation is mentioned as AE then on same AE page 'Action taken with investigational product' must recorded/selected as 'Investigational product withdrawn'. Please reconcile the data and update as appropriate. Thank you.' answered with 'updated Dosing Discontinuation to include AE description, Action taken w/ IP states I/P withdrawn.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:53:52
User opened query 'Per CDM: Please check on Dosing Discontinuation form Primary reason for dosing discontinuation is mentioned as AE#1. Per CCG If reason for discontinuation is mentioned as AE then on same AE page 'Action taken with investigational product' must recorded/selected as 'Investigational product withdrawn'. Please reconcile the data and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 18:26:36
Query 'Per CDM: Per CCG Only one AE should be recorded with IP Withdrawal Please note For AE# 1 Action taken with investigational product is marked as 'Investigational Product Withdrawn' Also on Dosing Discontinuation form 'Primary reason for dosing discontinuation' is mentioned as AE #1. Kindly reconcile the data and update as appropriate. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 18:21:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:34

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCG Only one AE should be recorded with IP Withdrawal Please note For AE# 1 Action taken with investigational product is marked as 'Investigational Product Withdrawn' Also on Dosing Discontinuation form 'Primary reason for dosing discontinuation' is mentioned as AE #1. Kindly reconcile the data and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 17:50:12
User closed query 'Per CDM: Per CCG Only one AE should be recorded with IP Withdrawal Please note For AE# 1 Action taken with investigational product is marked as 'Investigational Product Withdrawn' Also on Dosing Discontinuation form 'Primary reason for dosing discontinuation' is mentioned as AE #1. Kindly reconcile the data and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:03:09
Query 'Per CDM: Per CCG Only one AE should be recorded with IP Withdrawal Please note For AE# 1 Action taken with investigational product is marked as 'Investigational Product Withdrawn' Also on Dosing Discontinuation form 'Primary reason for dosing discontinuation' is mentioned as AE #1. Kindly reconcile the data and update as appropriate. Thank you.' answered with 'AE#1 updated. Only this AE reflects the reason drug was withdrawn' (Site from DM).	Nick Bart (b) (4)	15 Feb 2021 20:39:48
User opened query 'Per CDM: Per CCG Only one AE should be recorded with IP Withdrawal Please note For AE# 1 Action taken with investigational product is marked as 'Investigational Product Withdrawn' Also on Dosing Discontinuation form 'Primary reason for dosing discontinuation' is mentioned as AE #1. Kindly reconcile the data and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 08:33:28
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 09:09:59

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Generated On: 12 Aug 2021 13:39:34

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' answered with 'confirmed correctly entered' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 19:58:26
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 05:36:39
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'I'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 19:09:10



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Nick Bart (b) (4)	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User entered '0'	System	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:12
User entered '0'	System	27 Oct 2020 19:09:10

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 21:45:12

US3952116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Xerosis, LLT: Xerosis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 14:38:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 14:38:36
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 14:37:28
User entered 'xerosis'	Nick Bart (b) (4)	23 Mar 2021 14:37:03



**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '16 Feb 2021'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:37:03



**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:37:03



**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Nick Bart (b) (4)	23 Mar 2021 14:37:03



**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '1'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:37:03

**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 14:37:03



**US3952116**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 14:37:03

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:39:34

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:39:25
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User closed query 'Per DM CLR: Per Diary Dose 1 Day 4, Pain at Injection Site/Underarm Gland Swelling or Tenderness/Any use of prescription pain reliever or prevents daily activity = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 12:09:41
Query 'Per DM CLR: Per Diary Dose 1 Day 4, Pain at Injection Site/Underarm Gland Swelling or Tenderness/Any use of prescription pain reliever or prevents daily activity = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Contacted subject who does not recall taking medication during this time.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 19:38:29
User opened query 'Per DM CLR: Per Diary Dose 1 Day 4, Pain at Injection Site/Underarm Gland Swelling or Tenderness/Any use of prescription pain reliever or prevents daily activity = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 06:05:46
User entered 'Yes (Y)'	Nick Bart (b) (4)	22 Sep 2020 18:43:48

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
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)	22 Sep 2020 18:45:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:45:02
Data point term sent to Coder	System	22 Sep 2020 18:44:26
User entered 'metformin'	Nick Bart (b) (4) (b) (4)	22 Sep 2020 18:44:13

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:44:13

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'diabetes'	Nick Bart (b) (4)	22 Sep 2020 18:44:13

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '1000'	Nick Bart (b) (4)	22 Sep 2020 18:44:13

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	22 Sep 2020 18:44:13

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:44:13



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'twice daily (BID)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:44:13

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:44:13

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	22 Sep 2020 18:44:13

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:44:13

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:34

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'un UNK 2007'	Nick Bart (b) (4)	22 Sep 2020 18:44:13

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:44:13

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	22 Sep 2020 18:44:13

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:44:13



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:44:13

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Sep 2020 18:44:13

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 18:44:13

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 18:44:13

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 10:12:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 10:12:40
Data point term sent to Coder Coding entries removed.	System Nick Bart (b) (4)	04 Jan 2021 20:29:27 04 Jan 2021 20:29:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:46:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:46:50
Data point term sent to Coder User entered 'allopurinol'	System Nick Bart (b) (4)	22 Sep 2020 18:45:28 22 Sep 2020 18:44:40

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:44:40

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User closed query 'Per DM CLR: Please update the indication to reflect the location or type GOUT. Review and update MH entry so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 09:09:07
Query 'Per DM CLR: Please update the indication to reflect the location or type GOUT. Review and update MH entry so there is an appropriate match. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 20:29:22
User entered 'GOUT [bilateral feet]' reason for change: New Information	Nick Bart (b) (4)	04 Jan 2021 20:29:19
User opened query 'Per DM CLR: Please update the indication to reflect the location or type GOUT. Review and update MH entry so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:51:22
User entered 'gout'	Nick Bart (b) (4)	22 Sep 2020 18:44:40

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '300'	Nick Bart (b) (4)	22 Sep 2020 18:44:40



US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	22 Sep 2020 18:44:40

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:39:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:44:40

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'once daily (QD)'	Nick Bart (b) (4)	22 Sep 2020 18:44:40

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:44:40

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	22 Sep 2020 18:44:40

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:39:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:44:40

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:34

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'un UNK 1997'	Nick Bart (b) (4)	22 Sep 2020 18:44:40

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:44:40



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	22 Sep 2020 18:44:40

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:44:40

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:44:40

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 18:44:40

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 18:44:40

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 18:44:40

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 17:04:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:04:30
Data point term sent to Coder Coding entries removed.	System Nick Bart (b) (4)	04 Jan 2021 20:30:29 04 Jan 2021 20:29:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:46:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:46:49
Data point term sent to Coder User entered 'colchicine'	System Nick Bart (b) (4)	22 Sep 2020 18:45:29 22 Sep 2020 18:45:10

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:45:10



US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User closed query 'Per DM CLR: Please update the indication to reflect the location or type GOUT. Review and update MH entry so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 09:09:20
Query 'Per DM CLR: Please update the indication to reflect the location or type GOUT. Review and update MH entry so there is an appropriate match. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 20:29:36
User entered 'GOUT [bilateral feet]' reason for change: New Information	Nick Bart (b) (4)	04 Jan 2021 20:29:33
User opened query 'Per DM CLR: Please update the indication to reflect the location or type GOUT. Review and update MH entry so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:51:31
User entered 'gout'	Nick Bart (b) (4)	22 Sep 2020 18:45:10

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0.6'	Nick Bart (b) (4)	22 Sep 2020 18:45:10

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	22 Sep 2020 18:45:10

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:45:10

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'once daily (QD)'	Nick Bart (b) (4)	22 Sep 2020 18:45:10

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:45:10

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	22 Sep 2020 18:45:10

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:45:10



US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:34

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'un UNK 1997'	Nick Bart (b) (4)	22 Sep 2020 18:45:10

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:45:10

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	22 Sep 2020 18:45:10

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:45:10

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:45:10

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 18:45:10

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 18:45:10

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 18:45:10



US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 18:47:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:47:51
Data point term sent to Coder	System	22 Sep 2020 18:46:30
User entered 'tramadol'	Nick Bart (b) (4) (b) (4)	22 Sep 2020 18:45:35

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:45:35

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'osteoarthritis'	Nick Bart (b) (4)	22 Sep 2020 18:45:35

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '50'	Nick Bart (b) (4)	22 Sep 2020 18:45:35

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	22 Sep 2020 18:45:35

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:45:35

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'three times daily (TID)'	Nick Bart (b) (4)	22 Sep 2020 18:45:35

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:45:35



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	22 Sep 2020 18:45:35

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:45:35

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:34

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'un Mar 2020'	Nick Bart (b) (4)	22 Sep 2020 18:45:35

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:45:35

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	22 Sep 2020 18:45:35

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:45:35

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:45:35

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Sep 2020 18:45:35



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 18:45:35

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 18:45:35

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 18:47:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:47:51
Data point term sent to Coder User entered 'lisinopril'	System Nick Bart (b) (4)	22 Sep 2020 18:46:32 22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'hypertension'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '10'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:46:02



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'un UNK 2015'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	27 Oct 2020 19:10:08
User entered 'Yes (Y)'	Nick Bart (b) (4)	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '22 Oct 2020' reason for change: Data Entry Error	(b) (4)	27 Oct 2020 19:10:08
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:46:02



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User entered '1'	System	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User entered '1'	System	22 Sep 2020 18:46:02

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:56
User entered '804 (804)'	System	22 Sep 2020 18:46:02

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 18:47:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:47:51
Data point term sent to Coder	System	22 Sep 2020 18:46:33
User entered 'pantoprazole'	Nick Bart (b) (4) (b) (4)	22 Sep 2020 18:46:26

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:46:26

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'acid reflux'	Nick Bart (b) (4)	22 Sep 2020 18:46:26

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '40'	Nick Bart (b) (4)	22 Sep 2020 18:46:26



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	22 Sep 2020 18:46:26

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:46:26

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'twice daily (BID)'	Nick Bart (b) (4)	22 Sep 2020 18:46:26

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:46:26

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	22 Sep 2020 18:46:26

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:46:26

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'un Aug 2020'	Nick Bart (b) (4)	22 Sep 2020 18:46:26

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:46:26



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	22 Sep 2020 18:46:26

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:46:26

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:46:26

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Sep 2020 18:46:26

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 18:46:26

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 18:46:26

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 18:48:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 18:48:39
	(b) (4)	
Data point term sent to Coder	System	22 Sep 2020 18:47:34
User entered 'sildenafil'	Nick Bart (b) (4)	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:46:57



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'erectile dysfunction'	Nick Bart (b) (4)	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '100'	Nick Bart (b) (4)	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'as needed (PRN)'	Nick Bart (b) (4)	22 Sep 2020 18:46:57

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:46:57



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'un UNK 2017'	Nick Bart (b) (4)	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:46:57

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:46:57



US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 19:35:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 19:35:30
Data point term sent to Coder Coding entries removed.	System	05 Jan 2021 19:35:12
	Nick Bart (b) (4)	05 Jan 2021 19:34:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 20:05:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 20:05:49
Data point term sent to Coder	System	22 Sep 2020 18:47:35
User entered 'amoxicillin'	Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 14:44:13
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	05 Jan 2021 19:34:34
User entered 'Dental infection' reason for change: Data Entry Error	Nick Bart (b) (4)	05 Jan 2021 19:34:30
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 02:41:45
User entered 'broken tooth'	Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '500'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered empty.	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '06 Aug 2020'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '0'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '07 Sep 2020'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User entered '1'	System	22 Sep 2020 18:47:33



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User entered '1'	System	22 Sep 2020 18:47:33

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:05
User entered '804 (804)'	System	22 Sep 2020 18:47:33

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 07:40:42
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' answered with 'correct as entered. No AE needed' (Site from DM).	Nick Bart (b) (4)	10 Dec 2020 20:21:52
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:00:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 19:07:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 19:07:52
Data point term sent to Coder	System	29 Sep 2020 18:59:18
User entered 'ibuprofen'	Nick Bart (b) (4)	29 Sep 2020 18:59:17

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:59:17

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'osteoarthritis'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:59:17

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '800'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:59:17

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'mg (mg)'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:59:17

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered empty.	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:59:17



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'as needed (PRN)'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:59:17

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered empty.	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:59:17

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'Oral (ORAL)'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:59:17

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered empty.	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:59:17

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '23 Sep 2020'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:59:17

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '0'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:59:17

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'No (N)' reason for change: New Information	(b) (4) Nick Bart (b) (4)	27 Oct 2020 19:10:58
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Sep 2020 18:59:17

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '22 Oct 2020' reason for change: New Information	(b) (4)	27 Oct 2020 19:10:58
User entered empty.	Nick Bart (b) (4)	29 Sep 2020 18:59:17



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	29 Sep 2020 18:59:17

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User entered empty.	System	29 Sep 2020 18:59:17

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User entered empty.	System	29 Sep 2020 18:59:17

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:10
User entered empty.	System	29 Sep 2020 18:59:17

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN CALCIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Oct 2020 19:04:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 19:04:23
Data point term sent to Coder	System	12 Oct 2020 19:03:14
User entered 'atorvastatin calcium'	Nick Bart (b) (4) (b) (4)	12 Oct 2020 19:02:24

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	12 Oct 2020 19:02:24

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 09:09:30
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' answered with 'Not given for worsening of condition' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 20:04:03
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 15:29:27
User entered 'hyperlipidemia'	Nick Bart (b) (4)	12 Oct 2020 19:02:24

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '10'	Nick Bart (b) (4)	12 Oct 2020 19:02:24



US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	12 Oct 2020 19:02:24

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	12 Oct 2020 19:02:24

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'once daily (QD)'	Nick Bart (b) (4)	12 Oct 2020 19:02:24

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	12 Oct 2020 19:02:24

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	12 Oct 2020 19:02:24

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	12 Oct 2020 19:02:24

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '06 Oct 2020'	Nick Bart (b) (4)	12 Oct 2020 19:02:24

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	12 Oct 2020 19:02:24



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	12 Oct 2020 19:02:24

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	12 Oct 2020 19:02:24

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	12 Oct 2020 19:02:24

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 19:02:24

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 19:02:24

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 19:02:24

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:16:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:16:51
User signature succeeded.	Mimi Van Der Leden (b) (4)	09 Apr 2021 20:16:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:58:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:58:11
Data point term sent to Coder	System	10 Nov 2020 19:16:10
User entered 'sodium chloride 0.9%'	Nick Bart (b) (4)	10 Nov 2020 19:15:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'dehydration'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User closed query 'Per CDM: Re-Query: Previous response noted. However, per CCG V3.0 page 45, please enter the dose for the previous or concomitant medication taken. If dose is unknown, enter "UNK" into the text field. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:24:09
Query 'Per CDM: Re-Query: Previous response noted. However, per CCG V3.0 page 45, please enter the dose for the previous or concomitant medication taken. If dose is unknown, enter "UNK" into the text field. Thank you. ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	05 Jan 2021 19:35:02
User entered 'UNK' reason for change: Data Entry Error	Nick Bart (b) (4)	05 Jan 2021 19:34:58
User opened query 'Per CDM: Re-Query: Previous response noted. However, per CCG V3.0 page 45, please enter the dose for the previous or concomitant medication taken. If dose is unknown, enter "UNK" into the text field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 09:35:20
User closed query 'Per CDM Re-query: Per previous query response 'Unknown at this time, pending medical records' please consider to keep this query in open status until the data is updated. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 09:35:20
Query 'Per CDM Re-query: Per previous query response 'Unknown at this time, pending medical records' please consider to keep this query in open status until the data is updated. Thank you. ' answered with 'Medical documentation does not specify volume administered' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 20:07:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 10:36:20
User opened query 'Per CDM Re-query: Per previous query response 'Unknown at this time, pending medical records' please consider to keep this query in open status until the data is updated. Thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 10:36:18

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:34

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'Unknown at this time, pending medical records' (Site from System).	Nick Bart (b) (4)	10 Nov 2020 19:16:26
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:15:38
User entered empty.	Nick Bart (b) (4)	10 Nov 2020 19:15:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'mL (mL)'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'other (OTHER)'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'continuous'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered empty.	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '22 Oct 2020'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '0'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered '23 Oct 2020'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	10 Nov 2020 19:15:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User entered empty.	System	10 Nov 2020 19:15:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User entered empty.	System	10 Nov 2020 19:15:38



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:15
User entered empty.	System	10 Nov 2020 19:15:38

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 19:06:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 19:06:21
Data point term sent to Coder	System	28 Jan 2021 19:06:00
User entered 'tramadol'	Nick Bart (b) (4) (b) (4)	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'neck/shoulder pain'	Nick Bart (b) (4)	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '50'	Nick Bart (b) (4)	28 Jan 2021 19:05:38

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'three times daily (TID)'	Nick Bart (b) (4)	28 Jan 2021 19:05:38



US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '14 Jan 2021'	Nick Bart (b) (4)	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	28 Jan 2021 19:05:38



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jan 2021 19:05:38

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Jan 2021 19:05:38

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BANOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 11:42:31
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 Mar 2021 11:42:31
Data point term sent to Coder	System	23 Mar 2021 14:42:34
User entered 'Banophen'	Nick Bart (b) (4) (b) (4)	23 Mar 2021 14:41:47

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	23 Mar 2021 14:41:47

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:34

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 11:42:24
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'per source Allergic Rhinitis is PMHx.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:44:21
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:24:44
User entered 'allergic rhinitis'	Nick Bart (b) (4)	23 Mar 2021 14:41:47

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '25'	Nick Bart (b) (4)	23 Mar 2021 14:41:47

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	23 Mar 2021 14:41:47



US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:41:47

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'once daily (QD)'	Nick Bart (b) (4)	23 Mar 2021 14:41:47

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:41:47

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	23 Mar 2021 14:41:47

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:41:47

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '18 Feb 2021'	Nick Bart (b) (4)	23 Mar 2021 14:41:47

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	23 Mar 2021 14:41:47

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	23 Mar 2021 14:41:47



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:41:47

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	23 Mar 2021 14:41:47

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 14:41:47

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 14:41:47

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 14:41:47

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Mar 2021 14:43:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 14:43:40
Data point term sent to Coder	System	23 Mar 2021 14:42:34
User entered 'loratadine'	Nick Bart (b) (4) (b) (4)	23 Mar 2021 14:42:18

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	23 Mar 2021 14:42:18

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'allergic rhinitis'	Nick Bart (b) (4)	23 Mar 2021 14:42:18



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '10'	Nick Bart (b) (4)	23 Mar 2021 14:42:18

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	23 Mar 2021 14:42:18

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:42:18

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4)	23 Mar 2021 14:42:18

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:42:18

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	23 Mar 2021 14:42:18

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:42:18

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '18 Feb 2021'	Nick Bart (b) (4)	23 Mar 2021 14:42:18



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	23 Mar 2021 14:42:18

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	23 Mar 2021 14:42:18

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:42:18

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	23 Mar 2021 14:42:18

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 14:42:18

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 14:42:18

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 14:42:18

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: FLUOCINONIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:43
Data point term sent to Coder	System	23 Mar 2021 14:43:35
User entered 'fluocinonide cream'	Nick Bart (b) (4) (b) (4)	23 Mar 2021 14:43:03



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	23 Mar 2021 14:43:03

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'xerosis'	Nick Bart (b) (4)	23 Mar 2021 14:43:03

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '1'	Nick Bart (b) (4)	23 Mar 2021 14:43:03

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Other (OTHER)'	Nick Bart (b) (4)	23 Mar 2021 14:43:03

US3952116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'application'	Nick Bart (b) (4)	23 Mar 2021 14:43:03

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'once daily (QD)'	(b) (4) Nick Bart (b) (4)	23 Mar 2021 14:43:03

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:43:03

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Topical (TOPICAL)'	Nick Bart (b) (4)	23 Mar 2021 14:43:03



US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:43:03

US3952116

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '18 Feb 2021'	Nick Bart (b) (4)	23 Mar 2021 14:43:03

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	23 Mar 2021 14:43:03

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	23 Mar 2021 14:43:03

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	23 Mar 2021 14:43:03

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	23 Mar 2021 14:43:03

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 14:43:03

**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 14:43:03



**US3952116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:39:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 14:43:03

**US3952116**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 12 Aug 2021 13:39:34**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 19:58:44

US3952116

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:39:34

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:52:55
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 22:52:53
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 22:52:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
	(b) (4)	
User entered '22 Oct 2020'	Nick Bart (b) (4)	03 Dec 2020 21:29:01

**US3952116**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 12 Aug 2021 13:39:34**

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:52:55
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
	(b) (4)	
User entered 'AE (specify) (ADVERSE EVENT)'	Nick Bart (b) (4)	03 Dec 2020 21:29:01

US3952116

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:39:34

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:52:55
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:16:06
User entered 'AE #2 [WORSENING OF BASELINE ELEVATED GRADE 3 BLOOD PRESSURE]'	(b) (4)	08 Apr 2021 22:50:48
reason for change: Data Entry Error	(b) (4), (b) (6)	
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 22:50:27
User entered 'AE #1 [WORSENING OF BASELINE ELEVATED GRADE 3 BLOOD PRESSURE]'	(b) (4), (b) (6)	08 Apr 2021 22:50:27
reason for change: Data Entry Error		
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:58:01
User closed query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4)	11 Dec 2020 10:22:42
Query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	10 Dec 2020 20:20:28
User entered 'AE #1' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 20:20:23
User opened query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:32:26
User entered 'Dehydration'	Nick Bart (b) (4)	03 Dec 2020 21:29:01